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Exhibit 1 — Proposed Amended Complaint and Its Exhibits

Exhibit 2 — Redlined Version of Amended Complaint

# **EXHIBIT 1**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

MORTON GROVE	)	
PHARMACEUTICALS, INC.	)	
	)	
Plaintiff,	)	No: 08-CV-1384
	)	
v.	)	Judge Bucklo
	)	Magistrate Judge Mason
THE NATIONAL PEDICULOSIS	)	
ASSOCIATION, INC.,	)	
	)	
Defendant.	)	<b>JURY TRIAL DEMANDED</b>
	)	
	)	
	)	

**AMENDED COMPLAINT**

Plaintiff, Morton Grove Pharmaceuticals, Inc. (“Morton Grove”), by and through its attorneys, Winston & Strawn LLP, for its Amended Complaint against the National Pediculosis Association, Inc. (the “NPA”), states:

**Nature of Action**

1. This is an action brought to redress false, misleading, and deceptive statements and comparative advertisements regarding two FDA-approved drugs—Lindane Lotion and Lindane Shampoo—prescribed for the treatment of lice and scabies.

2. Plaintiff Morton Grove is a pharmaceutical company. Defendant NPA is the distributor of the LiceMeister® Comb, which competes with Lindane medications. While the NPA refers to itself as an “agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies

pesticidal treatments” and masquerades as a health organization, upon information and belief, the NPA does not employ a single physician or licensed health professional. It is a competitor of Morton Grove. In fact, in 2003, 97% of the NPA’s revenues were derived through the sale of LiceMeister® combs.

3. Morton Grove brings this action against the NPA for violation of the Lanham Act, trade disparagement, and violation of the Illinois Deceptive Trade Practices Act.

4. Morton Grove is the only United States manufacturer and distributor of Lindane medications. As such, the NPA’s statements regarding “lindane” necessarily refer to Morton Grove and its products.

5. Lindane medications have been approved by the Food and Drug Administration (“FDA”) as safe and effective prescription therapy for the treatment of lice and scabies. These infections, some of which are sexually transmitted, are increasingly resistant to certain treatments and remain important public health problems that affect tens of millions of Americans each year.

6. In the 50+ years that Lindane medications have been on the market, subject matter experts working with the FDA and the Environmental Protection Agency (“EPA”) have reviewed the weight of medical and scientific evidence on Lindane medications and repeatedly determined that these medications are safe and effective when used as directed. The FDA has consistently maintained its position that the benefits of Lindane medications outweigh the risks—a factor for all medications—and should remain an option for physicians. Petitions, including

one filed by the NPA, to ban Lindane medications have repeatedly been denied and determined to be without merit.

7. Similarly, the EPA has concluded that pharmaceutical Lindane poses no significant risk to humans or the environment when used as currently labeled.

8. The public health benefits of Lindane medications are further supported by the recommendations of the Centers for Disease Control and Prevention (“CDC”). The CDC sets practice standards for the medical community and includes Lindane medications in its Sexually Transmitted Disease Treatment Guidelines for the management of scabies and pubic lice, consistent with the FDA-approved prescription labeling for Lindane Lotion and Lindane Shampoo.

9. Moreover, in 2003, important advancements to the packaging and prescription of Lindane medications manufactured and sold in the United States served to mitigate the potential risks associated with product misuse and further enhanced their public safety.

10. Lindane Lotion and Lindane Shampoo are named after their active ingredient, lindane. Historically, lindane was used primarily in an agricultural context—more than 99% of lindane was used agriculturally, while less than 1% was used pharmaceutically (e.g., 99.7% agricultural v. 0.3% pharmaceutical in 2006). The dangers associated with chronic occupational exposure to agricultural lindane have been widely and unfavorably reported. These dangers differ vastly from those associated with the short-term topical application of small amounts of Lindane medications to the hair and skin—just 4 minutes in the case of head lice.

11. Despite this well-documented scientific, medical, and regulatory history, the NPA has launched an attack campaign on Lindane medications. The NPA swaps agricultural and pharmaceutical research, selectively quoting and/or misstating findings from studies relating to the agricultural use of lindane, and widely disseminates false, misleading, and deceptive statements about the safety profile and effectiveness of Lindane medications. These statements have created confusion in the marketplace and affected purchasing and prescribing behavior, negatively impacting both the sale of Lindane medications and Morton Grove's business.

#### **Parties**

12. Morton Grove, a Delaware corporation, is a pharmaceutical company with its principal place of business in Morton Grove, Illinois.

13. Upon information and belief, the NPA, a Massachusetts corporation, is based in Needham, Massachusetts. The NPA widely distributes information and products nationally, including in Illinois, through its interactive websites [www.headlice.org](http://www.headlice.org) and [www.lindane.org](http://www.lindane.org), which attract as many as 100,000 hits per day from thousands of unique visitors in the United States and around the world. The NPA sells its products nationally and has profited from the sales of the LiceMeister® comb in Illinois.

### **Jurisdiction & Venue**

14. This Court has jurisdiction over the subject matter of this action based upon the federal question presented by the Lanham Act, 15 U.S.C. § 1125(a) et seq., pursuant to 28 U.S.C. § 1331, and supplemental jurisdiction of the state law claims pursuant to 28 U.S.C. § 1367.

15. The Court has jurisdiction over the NPA based on their substantial contacts with the State of Illinois, including their commission of tortious acts which caused injury in the State of Illinois.

16. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

### **Factual Allegations**

#### **I. Background on Lindane Medications**

17. Morton Grove is the sole United States distributor of Lindane Shampoo and Lindane Lotion.

18. Lindane Lotion and Lindane Shampoo are prescription medications for the treatment of scabies, pubic lice, and head lice. These conditions are highly contagious public health conditions, some of which are sexually transmitted. These diseases affect adolescents, adults, and children, causing significant morbidity that impacts tens of millions of Americans.

19. Lindane medications have been used successfully in clinical practice for more than 50 years.

20. The FDA and the EPA, after numerous exhaustive reviews of the weight of evidence on Lindane medications, have concluded that currently approved

medical uses of Lindane medications do not pose a significant risk to public health or safety. In fact, Lindane medications have been reviewed by the FDA more than a dozen times beginning in 1951, and with each review the “FDA has determined that lindane products have benefits that outweigh risks when used as directed.” Woodcock, J. (Director, FDA Center for Drug Evaluation and Research), “Re: Docket No. 95P-0018/cP,” Correspondence to Jill A. Cashen, Cancer Prevention Coalition, May 13, 1997; U.S. Food and Drug Administration, Lindane Assessment Memorandum (2003). In 2001, the EPA even downgraded the cancer classification of lindane to a level that is in fact lower than the most commonly used first-line, over-the-counter medication permethrin (active ingredient in Nix®), and concluded that no additional cancer risk assessments of lindane in humans were necessary.

21. The CDC and the American Academy of Pediatrics (“AAP”) both recommend pediculicidal treatments—which Lindane medications are considered—over wet combing for the management of head lice, as combing leads to dramatically lower rates of clinical cure than chemical treatments.

## **II. The NPA Attempts to Increase Sales of the LiceMeister® by Distributing False, Misleading, and Deceptive Advertisements Regarding Lindane Medications**

22. Blindly ignoring well-established science and the positions of the FDA, EPA, CDC, and AAP on Lindane medications, the NPA has launched an attack campaign against Lindane medications in the hopes that it can increase sales of the LiceMeister® comb. This for-profit campaign blatantly ignores all standards for comparative marketing, including those promulgated by the FDA’s Division of Drug



Marketing and Advertising, which prohibit all such advertisements unless the representations made in those advertisements are supported by substantial evidence derived from adequate and well-controlled studies. See 21 U.S.C. § 355(d). In addition, the NPA violates norms and rules of advertising established by the FTC. See 15 U.S.C. § 45; 15 U.S.C. § 52; 16 C.F.R. § 14.15. Examples of the NPA's false advertising claims and other false statements referenced infra are attached as Exhibit A. Recent NPA employees admitted in depositions that they have no scientific background or training, did nothing to verify that the posted material was correct, and did not vet the information with any scientists or licensed medical professionals.

23. On this commercial website, the NPA has posted several hundred MedWatch forms which it has completed. MedWatch forms are typically used by consumers and their healthcare providers to report to the FDA adverse experiences that consumers have had with various drugs. Here, the NPA solicits data from visitors to its website, uses that data to complete MedWatch forms, signs its name to these forms as the reporter, and submits the forms the FDA. Next to its name, the NPA indicates that it is a "Health professional."

24. In fact, the NPA is not a "Health professional"—none of the members of its Board of Directors and none of its employees are licensed healthcare professionals, such as physicians, pharmacists, or nurses. Nor does the NPA have any proximity to or involvement in the actual treatment of the patient, as is typical when a medical professional submits a MedWatch form. The repeated

representations that the NPA is a “Health professional” are false and misleading, contribute to the illusion of medical credentials that the NPA projects on its website, and are part of the context in which the NPA’s false statements were made.

25. The overall context and message of the NPA’s website, identified in Paragraph 13, and statements creates with the viewer a false impression that misrepresents: (1) Lindane medications’ effectiveness; (2) Lindane medications’ harm to the environment; (3) that if you use Lindane medications, you significantly increase the risks of developing cancer and other serious adverse health effects; and (4) the NPA’s statements are objective, represent the scientific norm, and come from scientifically- and medically-credentialed individuals.

26. In an effort to maximize profits, the NPA has falsely claimed that the “symptoms” from “exposure” to Lindane medications include:

acute renal failure with azotemia, ADD/ADHD[,] anxiety, autism, atonia, agranulocytosis, aplastic anemia, anorexia, apprehensive mental state, behavior-mood disturbances, bullae, cancer, cardiac arrhythmias, clumsiness, coma, confusion, conjunctivitis, convulsions, cough, cyanosis, death, dermatitis, diaphoresis, diarrhea, disorientation, dizziness, dyspnea, emotional lability, excitement, excessive hair growth, fast heartbeat, fatigue, fever, giddiness, grinding teeth, headaches, heart palpitations, hematuria, hyperirritability, hypersensitivity, incoordination, kidney damage, liver damage, liver enlargement, loss of appetite, mania, mental retardation, muscle cramps, muscle spasms, muscle tremors, nausea, nervousness, oliguria, pallor, paraesthesia, paresis, paresthesia, porphyria, proteinuria, pulmonary edema, restlessness, respiratory failure, seizures, shaking, sweating, tachycardia, tearing, thirst, trouble breathing, trouble swallowing, urticaria, vertigo, vomiting, weakness, wheezing, elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes.

27. In fact, the overwhelming majority of these so-called symptoms or side effects nowhere appear on the FDA-approved prescription label for Lindane Lotion or Lindane Shampoo and are not reflected in the events reported to the FDA through its Adverse Event Reporting System Database or to the manufacturer.

28. In addition to mischaracterizing the safety profile of Lindane medications, the NPA has also misclassified its regulatory status, claiming "Illinois Bans Lindane" and "Illinois Banned Lindane." The truth is that Illinois has not banned lindane. Following the filing of Morton Grove's complaint, the NPA removed these false statements from its website.

29. The NPA's website also falsely claims that "one dose of a lindane treatment for head lice can pollute 6 million gallons of water to levels exceeding drinking water standards."

30. Like many of the NPA's other statements, this statement is scientifically unsubstantiated and runs counter to the conclusions of subject matter experts working with the EPA. In fact, the EPA has determined in its most recent assessment of lindane that the amount of pharmaceutical lindane reaching drinking water supplies is insignificant and not of concern.

31. Even unrealistic, worst-case estimates show that if Lindane medications were dumped directly into the drinking water supply (and not washed down the drain and out of the water supply and then diluted many thousand fold when reintroduced into large bodies of water as would normally occur), lindane

levels would still be 67 to 333 times lower than the level considered safe by the EPA.

32. These findings are further reinforced by real-world data from large-scale water contamination studies which show that lindane is not a water contaminant of concern, and that levels—when rarely detected—are well below standards established by the EPA for safe drinking. For example, a 2003 survey of water contamination, which involved the testing of 16,000 water systems serving 100 million people across the US, conducted by the EPA found that 0% exceeded conservative levels considered safe. Federal Register 68(138) (July 18, 2003). Similar findings were noted by the United States Geological Survey in 1999 and 2000 where water samples near large cities and farms were tested across 30 states and all found to be well within established EPA standards. Kolpin DW, Furlong ET, Meyer MT, et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. streams, 1999–2000: A National Reconnaissance. *Environ Science Technology*, 2002; 36(6):1202–1211.

33. In addition, an almost identical statement was retracted by the NPA's former co-defendant, the Ecology Center, Inc., who noted that the EPA “does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use [of lindane] for both lice and scabies.” See <http://www.ecocenter.org/safekids/clarifications.pdf>.

34. The NPA has received information from Morton Grove and others that its claim that "one dose of lindane" contaminates 6 million gallons of drinking water is false and misleading.

35. Despite knowledge of this statement's falsity, it remains on the NPA's website today.

36. The NPA does not stop there in its efforts to "scare" consumers into using its product, the LiceMeister® comb; it also attempts to convince consumers that using Lindane medications cause cancer. For example, it argues that: "[T]he U.S. EPA classif[ies] lindane as a possible human carcinogen" and "Lindane should be handled as a **CARCINOGEN WITH EXTREME CAUTION.**"

37. This statement is false and is not supported by the weight of scientific evidence or determinations published by the EPA, World Health Organization, and other subject matter experts.

38. In fact, the NPA's former co-defendant, the Ecology Center, Inc. issued a retraction noting that current information on the EPA's website notes that the EPA updated the cancer classification of lindane in 2003 to "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans." See <http://www.ecocenter.org/safekids/clarifications.pdf>

39. Lindane's carcinogenic risk is now considered by the EPA to be on par with malathion (active ingredient in FDA-approved lice treatment Ovide) and even lower than the most commonly used first-line, over-the-counter treatment permethrin (active ingredient in Nix).

40. The NPA also has stated: “Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos.” There, however, have been no established links between the use of Lindane medications and the development of cancer, despite more than 50 years of clinical use on adults and children. The “case-controlled” research cited by the NPA prompted a special review by the FDA that subsequently concluded: “[I]t was unlikely that the data in the Davie et al. study established any link between the increased incidence of childhood brain cancer and the use of Lindane 1% . . . shampoo, and that there was no need to make any changes in the current labeling for [Lindane medications].”

41. The NPA has also claimed that: “Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death.”

42. With respect to the NPA’s allegation that the use of lindane medications is associated with leukemia, the NPA’s former co-defendant, the Ecology Center, retracted a similar statement, which notes that in this particular study, only “[s]ix of the 568 children participating in this study were treated with lindane shampoo.” As the Ecology Center conceded, the study’s only conclusion with respect to lindane medications was that the issue “requires further study” in light of the “reported 95% confidence interval for lindane was CI 0.5 to 8.7,” which

is not statistically significant.

See

<http://www.ecocenter.org/safekids/clarifications.pdf>.

43. In a further effort to divert customers from Lindane medications to the LiceMeister® comb, the NPA's website also contains the following false and deceptive statements and misleading "warnings":

- "Be Sure You Provide a Non-Chemical Choice For Your Children . . . Because it's not worth taking unnecessary risks when the bottom line will always be the manual removal of lice and nits."
- "Never resort to **dangerous remedies** such as lindane, kerosene, or pet shampoos." (emphasis supplied).
- "When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school safe, lice and nit free."
- "Do not recommend products containing lindane. The Food and Drug Administration (FDA) regards it as potentially more toxic than all other pediculicidal choices and no more effective."

44. Finally, in an effort to sell additional LiceMeister® combs, the NPA has attempted to scare potential and actual consumers of Lindane medications with a "parade of horrors" regarding the effects of occupational exposure to agricultural lindane. These statements include:

- "Lindane is quite toxic to humans. The acute (short-term) effects of lindane through inhalation exposure in humans consist of irritation of the nose and throat and effects on the blood and skin. Chronic (long-term) exposure to lindane by inhalation in humans has been associated with effects on the liver, blood, and nervous, cardiovascular, and immune systems."
- "Chronic effects include damage to the nervous system and liver disease. Worker exposures have resulted in blood disorders, headaches,

convulsions, and disruption of the reproductive hormones of the endocrine system.”

45. These statements are wildly misleading in context, as the FDA has concluded that the “risk of occupational/environmental exposure should be assessed separately and independently of the risk related to the therapeutic use of a medication to treat a medical condition where there is a direct benefit to the patient.” The EPA shares this position.

46. Indeed, the NPA’s former co-defendant, the Ecology Center, Inc. published a retraction that clarifies this, noting that “the majority of such [adverse reactions] have resulted from oral ingestion (which is not how lindane medications are directed to be applied).” See

<http://www.ecocenter.org/safekids/clarifications.pdf>.

47. Upon information and belief, the NPA has never performed, prior to publication of the aforementioned statements, any tests comparing the qualities and characteristics of the LiceMeister® comb and Lindane medications, or evaluating the qualities and characteristics of Lindane medications.

### **III. As a Result of the NPA’s Actions, Morton Grove Has Been Harmed**

48. As a result of the NPA’s foregoing statements, Morton Grove has suffered incalculable financial and reputational injury to its business, including lost sales of Lindane medications and diminished goodwill.

49. The NPA’s statements, for example, contributed to a decrease in Morton Grove’s sales of 23%, or \$9.3 million, from January 2006 to November 2006.



50. The NPA's statements are viewed up to 100,000 times per day on the NPA's website, and they have deceived consumers and physicians into falsely questioning the safety and effectiveness of Lindane medications, thereby materially affecting purchasing and prescribing behavior for Lindane medications.

51. Moreover, the NPA has crafted its website in a manner to most effectively disseminate the aforementioned false and misleading statements, directing users to "see what we want them to see and avoid what we don't."

52. The NPA itself has acknowledged that its statements have affected Morton Grove's sales, noting that "sales figures for lindane products (Kwell, etc.) have fallen dramatically . . . . By targeting parents for re-education along with health professionals, we have ensured that the message travels up as well as down, and takes root in the process."

#### **IV. The NPA's Statements Were Made Intentionally & Maliciously**

53. In light of the statements' significant impact on Morton Grove's business, Morton Grove sent the NPA a letter (attached as Exhibit B) indicating that the NPA was publishing false, misleading, and deceptive statements about Lindane medications which were harming Morton Grove. This letter detailed each such false statement (either identical or similar to those included in this complaint), provided factual support for why each statement was false, and gave the NPA time to retract such statements. In addition, Morton Grove previously filed suit against the NPA on February 6, 2007 in the Northern District of Illinois (No. 06-CV-3815), from which this action was severed.

54. Despite this opportunity, the NPA failed to retract its false, misleading, and deceptive statements and continues to allow the publication and dissemination of these statements, even after receiving information that certain of these statements were false.

55. The NPA's continued publication of these statements, despite knowing their falsity, demonstrates the NPA's malicious intent to inflict harm on Morton Grove.

**COUNT I**  
**LANHAM ACT (15 U.S.C. § 1125(a))**

56. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 55 of this Complaint.

57. The NPA sells a lice treatment product called the LiceMeister®, which it promotes as an alternative to Lindane medications.

58. The NPA's statements, through its website and sales of its product, have been made in interstate commerce and were, are, and continue to be made intentionally and willfully.

59. The NPA's advertising claims set forth above are false and misleading descriptions and representations of fact about Lindane medications. In addition, these statements are misleading in context and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

60. The NPA's false and misleading advertising claims have deceived and have the tendency to deceive a substantial portion of the target audience for lice and scabies treatments.

61. The NPA's false and misleading advertising claims are material to consumers' purchasing decisions.

62. The NPA has caused its false and misleading advertising claims to enter into interstate commerce.

63. The NPA's false and misleading advertising claims have caused certain consumers to not purchase Lindane medications. These claims have caused and are continuing to cause damage to Morton Grove's sales and market share and injury to Morton Grove's goodwill and business reputation, warranting injunctive relief.

64. The NPA's false and misleading claims were made deliberately and willfully, and the NPA knew or should have known that these statements were false and that the impact of its statements would be to reduce sales of Lindane medications. Therefore, Morton Grove seeks a finding that this is an exceptional case, requiring an award of attorney fees to Morton Grove.

65. The NPA's continued use of false or misleading advertising claims is causing great irreparable injury to Morton Grove, thereby warranting an order granting permanent injunctive relief.

**COUNT II**  
**TRADE DISPARAGEMENT**

66. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 65 of this Complaint.

67. The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs 26 through 45.

68. The statements regarding Lindane medications set forth in Paragraphs 26 through 45 are false and misleading.

69. The NPA published and communicated these statements through its website and other means.

70. When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove.

71. As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs 48 through 52.

**COUNT III**  
**ILLINOIS DECEPTIVE TRADE PRACTICES ACT (815 ILCS 510/2)**

72. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 71 of this Complaint.

73. The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs 26 through 45.

74. The statements regarding Lindane medications set forth in Paragraphs 26 through 45 are false and misleading.

75. When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove. Specifically, prior to filing its Complaint, Morton Grove provided the NPA

with specific scientific proof that certain of its statements were false and misleading. The NPA did not substantively respond to Morton Grove's letter.

76. These statements violated multiple sections of 815 ILCS 510/2, including subsections (2), (7), (8), and (12).

77. As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs 48 through 52.

**WHEREFORE**, Plaintiff, MORTON GROVE PHARMACEUTICALS, INC., requests this Honorable Court for the following relief:

A. An Order (i) permanently enjoining the NPA from further dissemination of false, misleading, and deceptive statements regarding Morton Grove and Lindane medications; (ii) permanently enjoining the NPA from future publication of the false, misleading, and deceptive statements contained in Paragraphs 26 through 45; and (iii) requiring the NPA to publish corrective advertising;

B. Morton Grove's court costs and reasonable attorney's fees; and

C. For such other and further relief as this Court deems equitable and just.

Dated: July 24, 2008

Respectfully Submitted,

MORTON GROVE  
PHARMACEUTICALS, INC.

By: s/ W. Gordon Dobie  
*One of its Attorneys*

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 24th day of July 2008, I caused a copy of the **Amended Complaint** to be served on counsel of record via ECF electronic filing:

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s/ William C. O'Neil

**Index of Exhibits**

Exhibit A — Statements published by the NPA

Exhibit B — Morton Grove's letter to the NPA



# **EXHIBIT A**



**News**  
Current Lice &  
Scabies News



**FAQs**  
Facts & Photos  
Prevention & Treatment



**Report**  
Adverse Reactions,  
Product Problems &  
Outbreaks



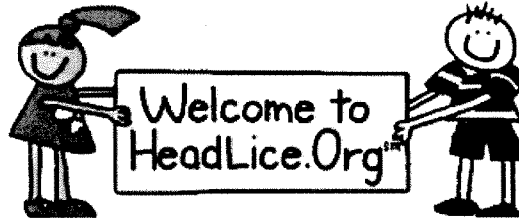
**Jesse's  
Project**  
Protecting Kids &  
Families



**Catalog**  
Educational Resources,  
and  
Free Downloads

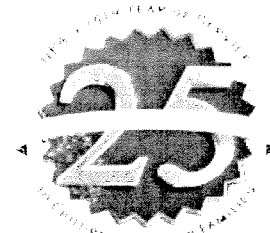


**Kids**  
Head Games,  
Bug Fun Activities



**The National Pediculosis Association®, Inc.**  
A Non-Profit Organization  
Serving the Public Since 1983

The LiceMeister® Comb  
more info



## September is Head Lice Prevention Month!



The LiceMeister® Comb was featured  
on the CBS series CSI. [\[view the clip\]](#)

- > Using The LiceMeister Comb
- > NPA Mission Statement
- > Suggest This Site to a Friend
- > Send an E-Card
- > Pollution Prevention Award
- > Lindane.org
- > Free Education Downloads
- > Press Releases
- > Site Search
- > Contact Us
- > HeadLice.org en Español
- > Malathion.org

### Make a Donation

The National Pediculosis Association is a non-profit, tax exempt organization that receives no government or pharmaceutical industry funding. Contributions are tax-deductible under the 501(c)(3) status. [Donate Now](#)

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Technical Questions or Problems?  
E-mail: [webmaster@headlice.org](mailto:webmaster@headlice.org)



Because it's not about lice, it's about kids.


National Pediculosis Association<sup>®</sup> Inc.  
[www.headlice.org](http://www.headlice.org)

Outline

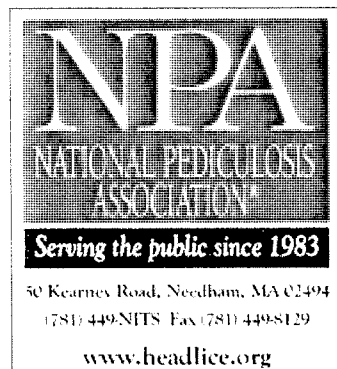


Slide 1 of 6



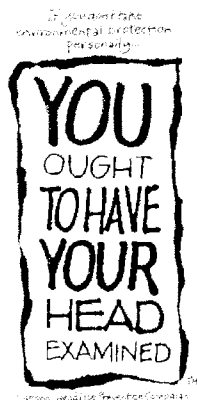
 Slide Show

# Who We Are



- The National Pediculosis Association (NPA) is a health and education 501(c)(3) non-profit organization established in 1983 to protect children from the harmful effects of pesticides used for the treatment of head lice.
- The NPA serves the public by providing independent and helpful information and resources so that pediculosis can be controlled safely and effectively.
- The NPA maintains its independence from product manufacturers through the sale of educational resources and its LiceMeister® comb.

# What We Do



*In 2001, the NPA and the Los Angeles County Sanitation District were awarded first prize by the National Pollution Prevention Roundtable for their work in the Lindane Usage Reduction Project, which resulted in the total ban of Lindane in the state of California.*

- **Prevention and Education**

Educating the public in advance of outbreaks is imperative in order to avoid panic and potentially harmful chemical responses. We encourage each family to do its part at home with routine screening, early detection, accurate identification and thorough removal of lice and nits.

- **Environment**

Many of the same chemicals potentially harmful to children when used to treat head lice and scabies also are harmful to the environment. For example, lindane, a prescription treatment for head lice, is a persistent bio-accumulative and toxic chemical. The Lindane Usage Reduction Project was the first major program to convince physicians to change the medications they prescribe based on environmental concerns.

- **Research**

The NPA is at the forefront of identifying lice resistance, issues associated with head lice and disease, new laboratory methods and related public health problems.

# Why We're Here

## Jesse's Project

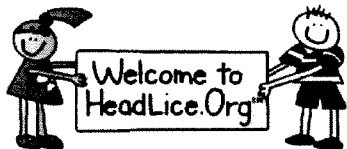
*Reaching out to families at a time when they need help...*



*Jesse's Project emphasizes prevention over chemical treatment and provides the tools to safely and effectively protect children with serious illnesses.*

- Head lice represent an important public health problem for children and families affecting more than 6 million school children each year.
- Traditional lice treatment products are pesticides and Americans spend over \$86 million on them annually.
- Children of any age or size are vulnerable to these chemicals, but none are more at risk than the growing number of children treated for illnesses such as cancer, brain tumors, epilepsy, asthma, allergies and AIDS. Jesse's Project addresses the critical need to protect these children.
- Parents want and need fewer pesticides in their family's lives. The NPA developed the LiceMeister Comb and LiceMeister Kit as the non-chemical treatment alternative.
- Recently published DNA research shows that head lice, like body lice, are potential carriers of disease.

# HeadLice.Org



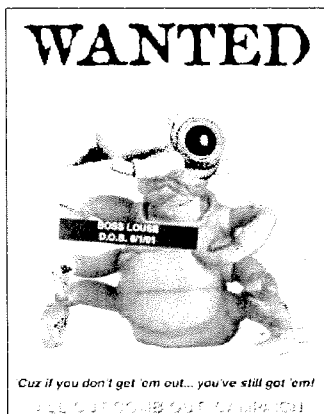
The National Pediculosis Association,® Inc.  
A Non-Profit Organization  
Serving The Public Since 1983.

*The #1 website for head lice information  
with visitors from over 92 countries  
throughout the world.*

*HeadLice.Org averages  
1 new visitor every 34 seconds!*

- The NPA's teaching website is consistently ranked first on Google, Yahoo! and other popular search engines.
- A monthly average of 90,000 unique visitors seek and obtain help from HeadLice.Org.
- HeadLice.Org is independent of head lice and scabies product manufacturers.
- HeadLice.Org hosts the National Reporting Registry for lice and scabies treatment failures and adverse events, reporting them monthly to the FDA's MedWatch program.

# NPA Sponsors National Pediculosis Prevention Month Every September



[www.headlice.org](http://www.headlice.org)

- In 1985, the NPA established September as National Pediculosis Prevention Month. In its' 20<sup>th</sup> consecutive year, this is the premiere back-to-school health message and is designated on health event calendars nationwide.
- The NPA drives the *All Out Comb Out*™ campaign all year long, promoting routine screening, early detection, accurate identification and thorough removal of lice and nits.
- The goal is to encourage the highest possible public health standard and enable children to be in school lice and nit free.



## Lindane Education And Research Network

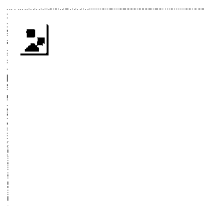
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Replacing one poison with another only continues to degrade the quality of all life.

[Lindane Index](#)[Chemistry](#)[Lindane](#)[Hexachlorobenzene](#)[Back](#)***gamma*-Hexachlorocyclohexane**

58-89-9



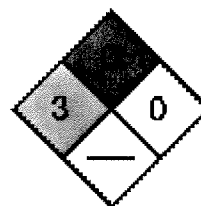
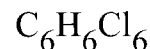
Enlarge image  
requires CHIME plug-in to view

(1 $\alpha$ ,2 $\alpha$ ,3 $\beta$ ,4 $\alpha$ ,5 $\alpha$ , $\beta$ )-1,2,3,4,5,6-  
hexachlorocyclohexane  
1 $\alpha$ ,2 $\alpha$ ,3 $\beta$ ,4 $\alpha$ ,5 $\alpha$ ,6 $\beta$ -hexachlorocyclohexane

1,2,3,4,5,6-Hexachlorocyclohexane (Gamma- Isomer)

## Names &amp; Synonyms

- Methods of Manufacturing
- Impurities
- Mechanism of Action
- International Regulation



Lindane (BHC)

W = 290.85

Melting Point = 112.5°C  
Boiling Point = 323.4°C @ MM HG

Slight musty or aromatic odor; Pure lindane is  
odorless.

COMMON NAME: GAMMA-BHC

## What is Lindane Anyway?

By any other name, lindane is the 99% pure gamma isomer of hexachlorocyclohexane. It was introduced as a pediculicide and scabicide in 1952 as Kwell by Reed and Carnrick. The Pharmaceutical Manufacturing Encyclopedia describes the manufacturing process of lindane as one in which **chlorine gas** is gradually passed into 660 parts of **benzene** (a known carcinogen) until 890 parts of the gas has been absorbed. The mixture is stirred continuously and the temperature is maintained at 15 degrees C to 20 degrees C.

The supply of **chlorine** is then interrupted and the precipitated solid filtered off and dried. In weight, it is found to be equivalent of 900 parts. The mother liquid is then mixed with 330 parts of **benzene** and the mixture again treated with 890 parts of **chlorine** in the manner described. After filtering the

reaction mixture resulting from the second **chlorination**, the filtrate is again mixed with a smaller quantity of **benzene** and again **chlorinated** in a similar manner. In this way, a continuous process for the preparation of **benzene hexachloride** results.

This benzene hexachloride isomer mixture is then the raw material for lindane production.  
[www.headlice.org](http://www.headlice.org)

---

## Methods of Manufacturing:

gamma-HCH is isolated by selective crystallization of crude HCH.

[Tomlin, C.D.S. (ed.). The Pesticide Manual - World Compendium, 11th ed., British Crop Protection Council, Surrey, England 1997 665]  
 \*\*PEER REVIEWED\*\*

Lindane is extracted from HCH by use of selected solvents, the most common ... is methanol. The gamma-isomer so obtained is treated with nitric acid to remove odor.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work)., p. V20 201 (1979)]\*\*PEER REVIEWED\*\*

Prepared by treating crude benzene hexachloride with methanol or acetic acid in which the alpha- and beta-isomers are nearly insoluble, followed by chromatographic adsorption or fractional crystallization.

[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed. Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present., p. VA14 280]\*\*PEER REVIEWED\*\*

**Benzene + chlorine (photochlorination/isomer separation).**

[Ashford, R.D. Ashford's Dictionary of Industrial Chemicals. London, England: Wavelength Publications Ltd., 1994. 539]\*\*PEER REVIEWED\*\*

TOXNET

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## Impurities:

Commercial lindane available in the US contains minimum of 99.9% (by wt) of gamma-isomer. The remaining 0.1% consists of other unspecified isomers of HCH.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work)., p. V20 199 (1979)]\*\*PEER REVIEWED\*\*

Crude benzene hexachloride consists of 10-18% of the gamma-isomer, 55-70% of the alpha- isomer, 5-14% of the beta-isomer, 6-8% of the delta-isomer, 3-4% of the epsilon-isomer, and a trace of the eta-isomer. A **heptachlorocyclohexane** and an **octachlorocyclohexane** are present as impurities and contribute to the unpleasant odor of benzene hexachloride.

[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed. Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present., p. VA14 280]  
 \*\*PEER REVIEWED\*\*

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## Mechanism of Action:

ITS MODE OF ACTION IS UNKNOWN BUT SPECIFIC TOXICITY OF GAMMA-ISOMER SUGGESTS THAT ... IT MAY INTERACT WITH PORES OF LIPOPROTEIN STRUCTURE OF INSECT NERVE CAUSING DISTORTION & CONSEQUENT EXCITATION OF NERVE IMPULSE TRANSMISSION.

[White-Stevens, R. (ed.). Pesticides in the Environment: Volume 1, Part 1, Part 2. New York: Marcel Dekker, Inc., 1971. 87]\*\*PEER REVIEWED\*\*  
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## European/International Regulations

European Labeling in Accordance with EC Directives Hazard Symbols:

T N Risk Phrases:

R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R 36/38 Irritating to eyes and skin.

R 50/53 Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

Safety Phrases:

S 13 Keep away from food, drink and animal feeding stuffs.

S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 60 This material and/or its container must be disposed of as hazardous waste.

S 61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

US DOT Shipping Name: ORGANOCHLORINE PESTICIDE,SOLID,TOXIC (RQ, LINDANE) Hazard Class: 6.1  
UN Number: UN2761 Packing Group: III

---

What is lindane?

For basic information see Lindane:2761.

NEXT PAGE

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## Lindane Education And Research Network

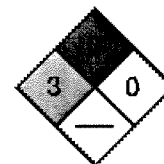
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Replacing one poison with another only continues to degrade the quality of all life.

## Lindane

Lindane is used as an insecticide on fruit and vegetable crops, for seed treatment, in forestry, and for animal treatment. It is no longer produced in the United States and aerial application of the chemical is prohibited; however, it is still formulated in this country. Lindane is also used topically for the treatment of head and body lice and scabies; it is available in 1% preparations as a lotion, cream, or shampoo.



Lindane is quite toxic to humans. The acute (short-term) effects of lindane through inhalation exposure in humans consist of irritation of the nose and throat and effects on the blood and skin. Chronic (long-term) exposure to lindane by inhalation in humans has been associated with effects on the liver, blood, and nervous, cardiovascular, and immune systems. The Reference Concentration (RfC) for lindane is under review by the U.S. Environmental Protection Agency (EPA).

Limited information is available on the reproductive or developmental effects of lindane in humans. Animal studies indicate that lindane causes reproductive effects, such as decreased sperm count, via oral exposure, while developmental effects, including birth defects, have not been noted. No studies are available on the carcinogenic effects of lindane in humans or animals via inhalation exposure. Oral animal studies have shown lindane to be a liver carcinogen. EPA has classified lindane as a possible human carcinogen of low to medium carcinogenic hazard.

The most probable route of lindane exposure in humans is oral ingestion of food containing the insecticide. Lindane may be released to the air during its formulation, from wind erosion of contaminated soil, or from release from hazardous waste sites. Lindane has been detected in groundwater and surface water samples collected near hazardous waste sites; however, the chemical has only very rarely been detected in drinking water supplies. Lindane has been listed as a pollutant of concern to EPA's Great Waters Program due to its persistence in the environment, potential to bioaccumulate, and toxicity to humans and the environment.

Lindane can be measured in the blood, urine, and semen of exposed individuals by gas chromatography.

CEHS website:  
<http://www.envtox.ucdavis.edu/CEHS/Index.htm>

[Back](#)

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# Lindane Education And Research Network

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"The future will depend"on our wisdom not to replace one poison with another."

*National Pediculosis Association<sup>®</sup>, Inc.*

## LINDANE (Hexachlorocyclohexane)

### What is Lindane?

Alpha- and Delta- Hexachlorocyclohexane are chemicals found in lindane which is commonly known as benzene hexachloride and HCH or BHC. Lindane is a white solid that may evaporate into air and has a slight musty odor. Although lindane is no longer produced in the United States, it continues to be imported and formulated in the United States for use there and in other countries. Lindane is a bioaccumulative chemical of concern (BCC) targeted by the Great Lakes Water Quality Initiative (GLI).

### Why Are We Concerned About Lindane?

Because lindane is bioaccumulative, it does not break down easily in our environment and becomes more concentrated as it moves up the food chain to humans and other animals.

### What Can You Do to Help?

You can help make the Great Lakes safe again by supporting speedy state adoption of the Great Lakes Initiative (GLI). Whether the chemical is banned or currently used, the GLI will tell us how much we have to clean up, work for pollution prevention, change policy, or work internationally to make our Great Lakes healthy. For more information on how you can become part of the solution, contact Campus Ecology for your Great Lakes Initiative Activist Kit at 313-769-9970 or Midwest@nwf.org or 506 E. Liberty, second floor, Ann Arbor, MI 48104-2210.

### What harmful effects can Lindane have on us?

- May cause cancer
- Reduces reproductive success
- Affects the central nervous system
- Alters sexual maturation in children
- Causes an increase in stillbirths
- Damages the liver

### How are we exposed to Lindane?

- In workplace air
- Breathing air surrounding plants where products using lindane are made

- By eating plants, meat, milk, or water that contain forms of lindane
- If used as a skin lotion to treat lice and/or scabies

### **Where can Lindane be found?**

Past uses:

- Insecticide on fruit, vegetable, and forest crops
- Household fumigant
- Insecticide on ornamentals and tobacco plants
- Used in feed storage areas
- Used for domestic outdoor and indoor uses by homeowners
- Used in commercial warehouses

Potential Sources to our Environment:

- Lindane in the air falls into our water via rain, snow, etc.
- Restricted use as a pesticide
- Restrictions on use for structural treatment
- Use on homeowner ornamentals
- Use on hardwood logs and lumber
- Soil and surface water near hazardous waste sites
- Runoff from soil and plants into water
- Improper use or disposal
- Dog shampoos
- Other household uses
- Seed treatment
- Moth sprays

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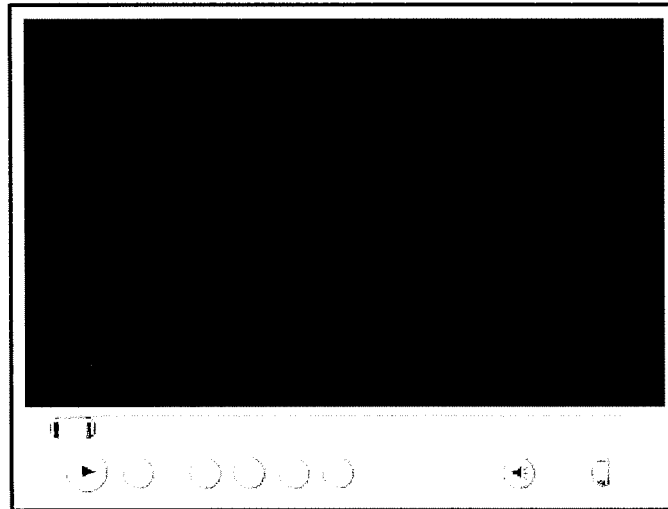
Please report any problems with this site to the webmaster

## What *is* Lindane Anyway?

For starters it is consistently ranked among the top chemicals of concern by the Agency for Toxic Substances and Disease Registry. By any other name, lindane is the 99% pure gamma isomer of hexachlorocyclohexane. It was introduced as a pediculicide and scabicide in 1952 as Kwell by Reed and Carnrick. The Pharmaceutical Manufacturing Encyclopedia describes the manufacturing process of lindane as one in which **chlorine gas** is gradually passed into 660 part of **benzene** (a known carcinogen) until 890 parts of the gas has been absorbed. The mixture is stirred continuously and the temperature is maintained at 15 degrees C to 20 degrees C.

The supply of chlorine is then interrupted and the precipitated solid filtered off and dried. In weight, it is found to be equivalent of 900 parts. The mother liquid is then mixed with 330 parts of benzene and the mixture again treated with 890 part of chlorine in the manner described. After filtering the reaction mixture resulting from the second chlorination, the filtrate is again mixed with a smaller quantity of benzene and again chlorinated in a similar manner. In this way, a continuous process for the preparation of benzene hexachloride results.

This benzene hexachloride isomer mixture is then the raw material for lindane production.



Requires Windows Media Player



### What does the Merck Index say about lindane?

According to the Centennial Edition of the Merck Index, poisoning with lindane may occur by ingestion, inhalation, or skin absorption; possible acute symptoms include headache, nausea, vomiting, diarrhea, tremors, weakness, convulsions, dyspnea, cyanosis circulatory collapse. The Merck Index states that "Lindane and other hexachlorocyclohexane isomers may reasonably be anticipated to be carcinogens."



### Is there a connection between lindane and seizures?

The proconvulsant properties of repeated low doses of lindane were reported by Joy and colleagues and it has been since this time that lindane has been used as a kindling agent for studying seizures in rats. M.E. Gilbert published her work with rats and lindane in, *Toxicology and Industrial Health*, Vol. 10, No. 4, 1994, *Neurotoxicology and Teratology*, Vol. 17, No 2 1995. Gilbert chose lindane for her studies because of its pharmacokinetic and pharmacodynamic properties well characterized in the rat. Those who think it is okay to keep prescribing lindane need to think again!

**The United States is one of very few industrialized countries still using lindane in agriculture and for lice control. Sign this petition to U.S. Surgeon General, Richard H. Carmona, urging him to call for an immediate ban on lindane.**

Visit [Lindane.org](http://Lindane.org) for more information.



### Statement in Support of the Elimination of Lindane Use in North America

In June 2002, the environment ministers from Mexico, the United States, and Canada resolved to develop a North American Regional Action Plan (NARAP) for lindane through the Commission for Environmental Cooperation of North America. The Task Force on Lindane will gather in Montreal, Canada September 28-30, 2004 to draft the NARAP.

We direct the following statement, supported by the undersigned non-governmental organizations in Mexico, the U.S. and Canada, to the North American Task Force on Lindane and the Ministers of Environment and Health from each country.

### Background



All three countries continue to allow pharmaceutical lindane use for pediculosis, lice, and scabies treatment. In Mexico, lindane is used mainly on livestock and as a seed insecticide for soil pest control. The 2002 U.S. Environmental Protection Agency (EPA) Re-registration Eligibility Decision allows lindane to be used as seed treatment for six grain crops: corn, wheat, barley, oats, rye, and sorghum. All remaining agricultural uses of lindane in Canada will stop on December 31, 2004.

## Findings

Lindane is a persistent, bioaccumulative, and toxic organochlorine insecticide. Lindane is banned by 17 countries. It is harmful to the environment and human health. Children are particularly vulnerable to the toxic effects of lindane. Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos. The International Agency for Research in Cancer (IARC) and the U.S. EPA classify lindane as a possible human carcinogen. Lindane is a potent neurotoxin, with symptoms from small exposures by ingestion or skin absorption ranging from nausea, dizziness, muscular weakness, tremors, and convulsions. Chronic effects include damage to the nervous system and liver disease. Worker exposures have resulted in blood disorders, headaches, convulsions, and disruption of the reproductive hormones of the endocrine system.

Lindane is highly persistent and travels long distances via atmospheric and oceanic currents. In fact, lindane, with its isomers, is the most abundant pesticide in Arctic air and water. Indigenous peoples of the north who rely on traditional diets of marine mammals and fish are particularly at risk from lindane exposure through foods. Lindane contaminates drinking water sources. The Los Angeles County Sanitation District estimates that one dose of a lindane treatment for head lice can pollute 6 million gallons of water to levels exceeding drinking water standards. This threat to clean drinking water, and the enormous costs of clean up, prompted California to ban lindane shampoos in 2002. Lindane is highly toxic to aquatic invertebrates, fish, and bees. It is a potential endocrine disruptor in birds, mammals, and possibly fish.

The undersigned organizations call upon the United States, Canada, and Mexico to specify the following actions in the in the North American Regional Action Plan for Lindane, applicable to each of the three countries:

- Rapid elimination of pharmaceutical, veterinary, and agricultural uses of lindane, with its use precluded given the availability of safer, affordable alternatives;
- Commitment to research and education programs that support alternatives to lindane, giving top priority to preventative and least-toxic alternatives;
- Delivery of education programs about the risks of lindane, emphasizing the protection of exposed populations of children, Indigenous peoples, and workers; and
- Active support for the expeditious inclusion of lindane among new substances added to the Stockholm (POPs) Convention for elimination as an Annex A substance.

### Organizations Supporting of the Elimination of Lindane in North America

Randy Virgin, Executive Director Alaska Center for the Environment Anchorage, Alaska U.S.A.	Pamela Miller, Executive Director Alaska Community Action on Toxics Anchorage, Alaska U.S.A.	Tom Atkinson, Executive Director Alaska Conservation Alliance/Alaska Conservation Voters Anchorage, Alaska U.S.A.
---	--	--

Andrea Carmen, Executive Director International Indian Treaty Council (IITC), an organization of Indigenous Peoples from North, Central, South America and the Pacific Palmer, Alaska, U.S.A.	Shawnee Hoover, Special Projects Director Beyond Pesticides/National Coalition Against the Misuse of Pesticides Washington D.C. U.S.A.	Gershon Cohen, Ph.D. Campaign to Safeguard America's Waters Earth Island Institute Haines, Alaska U.S.A. Karen Wristen, Executive Director Canadian Arctic Resources Committee Ottawa, Ontario, CANADA
Maite Cortés Colectivo Ecologista Jalisco MEXICO	Mindahi Crescencio Bastida-Muñoz, President Consejo Mexicano para el Desarrollo Sustentable MEXICO	Bob Shavelson, Executive Director Cook Inlet Keeper Homer, Alaska U.S.A.
Erik Jansson, Executive Director Department of the Planet Earth Washington D.C. U.S.A.	Sharon Labchuk Earth Action Prince Edward Island, CANADA	Joe DiGangi, Ph.D. Environmental Health Fund Chicago, Illinois, U.S.A.
Bill Smedley, Executive Director GreenWatch Inc. Jersey Shore, Pennsylvania U.S.A.	Manna Jo Greene, Environmental Director Hudson River Sloop Clearwater, Inc. Poughkeepsie, New York U.S.A.	Patricia Diaz Huicholes y Plaguicidas MEXICO
Tom Goldtooth, Executive Director Indigenous Environmental Network Bemidji, Minnesota, U.S.A.	Angel Valencia, Coordinator Indigenous Network Against Pesticides Members in 8 countries	Jerry Troshynski, President Alaska Public Health Association Anchorage, Alaska U.S.A.
Jo Behm, M.S., R.N., Co-President Marin Golden Gate Learning Disabilities Association San Francisco, California U.S.A.	Gina Solomon, M.D., M.P.H. Natural Resources Defense Council Assistant Clinical Professor of Medicine, U.C. San Francisco San Francisco, California, U.S.A	Arthur Hussey, Executive Director Northern Alaska Environmental Center Fairbanks, Alaska U.S.A.
Kristin Schafer, Program Coordinator Pesticide Action Network North America San Francisco, California U.S.A.	Fernando Bejarano Red de Acción sobre Plaguicidas y Alternativas en Mexico (RAPAM) MEXICO	Clayton Thomas-Muller, Coordinator Resisting Environmental Destruction on Indigenous Lands (REDOIL) Network Vancouver, British Columbia CANADA
Ted Schettler, M.D., Science Director Science and Environmental Health Network Boston, Massachusetts U.S.A.	Irene Alexakos Sierra Club, Alaska Chapter Haines, Alaska U.S.A.	Kenyon Fields, Executive Director Sitka Conservation Society Sitka, Alaska U.S.A.
Phillip Dickey, Staff Scientist Washington Toxics Coalition Seattle, Washington U.S.A.	Aimee Boulanger, Executive Director Women's Voices for the Earth Missoula, Montana U.S.A.	Clifton Curtis, Director, Global Toxics Program World Wildlife Fund Washington D.C. U.S.A.

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## The NPA's efforts to eliminate lindane get a huge boost

**NPA Press Release**  
11/01/01

The National Pediculosis Association (NPA) and Los Angeles County Sanitation District's (LACSD) efforts to eliminate lindane got a huge boost from an impressive list of other organizations during the time for public comment on the EPA's Preliminary Risk Assessment for Lindane.

Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death. Lindane is an unnecessary risk to all forms of life and for this reason has been banned in pharmaceutical products the state of California. The goal is not just to eliminate lindane, but also to ensure it is not replaced with yet another poison.

Advising the EPA in their risk assessment, The Natural Resources Defense Council (NRDC) Senior Scientist Gina M. Solomon, M.D., M.P.H., submitted comments on behalf of NRDC, Commonweal, Institute for Agriculture and Trade Policy, Northwest Coalition for Alternatives to Pesticides, Physicians for Social Responsibility-Los Angeles & San Francisco Bay Area, and Washington Toxics Coalition. Their joint statement strongly advises the EPA to correct the major flaws in their lindane risk assessment. Dr. Solomon summarizes, "On reviewing the literature on lindane's persistence, bioaccumulation in the environment and in human tissues, and toxicity, we do not believe that this chemical can safely be registered for use in the United States."

Also participating in this effort were The Alaska Community Actions on Toxics, Breast Cancer Action, Environmental Health Coalition, KidSource, Northwest Coalition for Alternatives to Pesticides, The Sierra Club, Tri-TAC, and the World Wildlife Fund.

The NPA and LACSD received the most prestigious pollution prevention award in the country for 2001. Senator Diane Feinstein commended the NPA and LACSD stating, "Your commitment to reducing lindane at the source represents a unique and innovative approach to protecting the environment. Lindane is a persistent bio-accumulative and toxic chemical that is dangerous to the environment, harmful to human health and threatening to the food chain. I was appalled to learn that lindane is still used to treat head lice."

The links below will take you to some examples of these letters.

<b>Letter submitted by The National Resources Defense Council</b>
<b>2nd Letter submitted by The National Resources Defense Council</b>
<b>Letter submitted by The NPA</b>
<b>Letter submitted by The World Wildlife Fund</b>
<b>Letter submitted by The Tri-TAC</b>
<b>Letter submitted by The LACSD</b>
<b>2nd Letter submitted by The LACSD</b>
<b>Letter submitted by The NYS Attorney General</b>

**Keep up the great work!**  
The NPA & LACSD want to commend these organizations

for their action and acknowledgement of the broad reaching effects lindane has on the public health and the environment:

Alaska Community Actions on Toxics
Breast Cancer Action
Commonweal
Environmental Health Coalition
Environmental Protection Agency - Region 9
Institute for Agricultural and Trade Policy
KidSource
National Resources Defense Council
The New York State Office of Attorney General
Northwest Coalition for Alternatives to Pesticides
Pesticide Action Network
Physicians for Social Responsibility - Los Angeles
Physicians for Social Responsibility - San Francisco Bay Area
The Sierra Club
Tri-TAC
The Washington Toxics Coalition
World Wildlife Fund

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**HeadLice.Org**<sup>SM</sup>**HeadLice.Org Hot Spots:**  
-- select a destination --

No matter what you do...

## **Be Sure You Provide a Non-Chemical Choice For Your Children, Their Families, Your Staff and Yourself!**

**Why?** Because children of any age or size are vulnerable to the harmful effects of pesticides. They also often have pregnant or nursing mothers who should never be exposed to chemical treatments either by applying them to themselves or to others.

**Why?** Because too many people unfortunately overuse chemical agents out of fear and frustration without adequate warning of the risks to themselves and the environment.

**Why?** Because each of us has our own unique vulnerabilities. Pesticide products can accumulate in the human body and they are not necessarily washed away at the end of the treatment, as people would like to think.

**Why?** Because the overuse of lice products can predispose a person to adverse reactions with even one additional chemical exposure.

**Why?** Because it's not worth taking unnecessary risks when the bottom line will always be the manual removal of lice and nits.

**Why?** Because none of the available chemical treatments are 100% effective and too many people are told to seek prescriptions after other treatments fail. Prescriptions become the most potentially harmful treatment of them all!

**Why?** Because pesticides pose a risk to all children, and none are more at risk than the growing number treated for illnesses and/or on medication.

**Why?** Because everyone needs a non-chemical way to screen and detect head lice early and remove them safely and effectively.

**Why?** "Cuz if you don't get 'em out, you've still got 'em!"<sup>TM</sup>

**"Because it's not about lice, it's about kids"<sup>TM</sup>**

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**A Non-Profit Organization**  
**Serving The Public Since 1983.**

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## Resistant Lice?

The NPA receives calls everyday from parents and health professionals reporting product treatment failure ... reports of folks using "everything on the drug store shelf," only to continue finding adult-sized crawling lice.

Unfortunately, frustrated parents have responded to persistent infestations by repeatedly using treatment products, or by resorting to dangerous alternatives. There are many elements that can play a role in treatment failure. While there is more than sufficient reason to seriously consider insect resistance, we must also acknowledge other possible contributing factors such as failure to follow product treatment instructions, failure to remove all nits, and false hope generated by product marketing promises.

Until the treatment failure crisis is fully addressed by the scientific and medical community as well as the product manufacturers, the NPA is offering the following suggestions for those who use a lice treatment product and experience treatment failure:

- If you continue to be infested with live lice after treatment, discontinue use of the products and don't use other products in the hope of killing the lice. Remember, these products are not mere shampoos, cremes or lotions, they are pesticides.
- Never resort to dangerous remedies such as lindane, kerosene, or pet shampoos.
- Manual removal is crucial. Beyond snipping or pulling out the nits, you should also be screening for and removing live lice. Having at least two people check an infested person is important as one person cannot see the entire scalp. Lice move quickly and shy away from light when you are checking.
- Don't spend hours on end cleaning your environment. Head lice need human blood to survive. Vacuum surface areas only. Save your time and energy for what will benefit you most, delousing the individual. NEVER USE A LICE SPRAY!
- When screening for lice with a nit-removal comb, it may be helpful to dip it into water and clean it before going to the next section of hair.
- Equip yourself and your helpers with a magnifying glass, tweezers, safety scissors, and a nit-removal comb.
- If you are experiencing treatment failure, please report it to the NPA's Registry by clicking here.

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## Pharmacist's Guide to Controlling Head Lice

With the exceptions of the common cold, head lice affect more school-aged children than all other communicable diseases combined. Studies show that the public wants to receive more advice from their pharmacist, and the trend in pharmacy practice is to provide more consultative services. All summed up, this means that pharmacists will, and should, assume a leadership role in the community effort to develop a sound and standardized approach to controlling head lice.

There is a lot of misinformation on this disease and its control. This is especially true on the Internet. There are many products being marketed as safe and natural alternatives yet labeled with pesticidal claims. The majority of these products have not been reviewed or approved by the Food and Drug Administration for human safety, manufacturing practices, or efficacy.

***Encourage everyone to get the facts and CHECK A HEAD.™***

**1. Determine if the patient has head lice: If there is not a diagnosis from a qualified health professional or knowledgeable parent, you may need to advise on how to identify an infestation.**

- A. When inspecting the scalp and hair, look for nits – tiny yellowish-white oval eggs firmly attached at an angle to the side of the hair shaft. Unlike what most pharmacists were taught in school, the nits a quarter inch from the scalp or further are not necessarily dead. Viable eggs can be found anywhere on the hair.
- B. An infestation is often detected by seeing nits rather than by finding head lice. Head lice, which shy away from the light and move quickly, may also be seen. They are the size of a sesame seed; are transparent as nymphs but with blood meals take on a reddish brown to black color.
- C. Using an effective screening device, such as the NPA's LiceMeister® comb, go through each section of hair from the scalp to the end of the hair. (Head lice can also be found in the eyebrows and eyelashes. Children should be examined by their physician in this situation.) Pesticides should not be used on or near the eyes.
- D. Be sure that patients do not confuse nits with hair debris such as desquamated epithelial cells (DEC plugs), which are bright white and irregularly shaped clumps of dandruff stuck to the hair shaft, or haircasts (elongated segments of dandruff that encircle the hair shaft). Both can occur in patients who have been over-treated with pesticides. Such debris can cause diagnostic confusion.
- E. Nits may be found throughout the hair, but are often found at the nape of the neck, behind the ears, and at the crown.
- F. Remind parents that routine screening and early detection is the best and only prevention. Pesticides should not be used to prevent head lice.
- G. Be mindful that some parents will assume that they or their children are infested whenever they hear that there is an outbreak. This is okay if it prompts them to screen... but not if it causes them to use pesticides unnecessarily.

**2. Alert those who are at greatest risk from the use of pesticides. These issues also apply to the person administering the treatment. Some of the factors impinging on the treatment choice include:**

- A. The health/age/size of the child.
- B. Whether the person applying or using the product is pregnant or nursing.
- C. Whether there are several infested family members to be treated by one parent.
- D. Individuals who have had repeated earlier pesticidal treatments.
- E. Patients on medication or with pre-existing medical conditions such as allergies, asthma, epilepsy, cancer, or with open wounds on the hands, scalp or neck.

### 3. Product Recommendations:

- A. Based on increasing reports of head lice resistance on a national level, the NPA advises parents to discontinue the use of head lice pesticides at the earliest sign of treatment failure. **MANUAL REMOVAL IS THE BEST OPTION WHENEVER POSSIBLE AND ESPECIALLY WHEN TREATMENT PRODUCTS HAVE FAILED.**
- B. Head lice treatments should be used over a sink, as opposed to a bath or shower as it will minimize the exposure of pesticides to the body. Caution against allowing these products to get near the eyes.
- C. Warn against the use of head lice sprays. Using head lice sprays on bedding, furniture, and carpets is unwarranted, has no scientific basis, and may pose personal and environmental hazards.
- D. Do not recommend products containing lindane. The Food and Drug Administration (FDA) regards it as potentially more toxic than all other pediculicidal choices and no more effective. None of the commercially available products will kill 100% of the nits.
- E. Provide educational materials about head lice control near the head lice products in the pharmacy, and encourage affected persons to discuss their experience with you.
- F. The current endemic nature of head lice among children challenges the traditional management concept that the lack of efficacy in pediculicides can be countered by retreating children in 7-10 days later to kill the newly hatched lice. The 7-10 day time span is nebulous. More importantly, such a measure does not take into account the opportunities to become reinfested from another child in the interim.

### 4. Additional Control Measures for Patients

- A. Have parents screen as part of personal hygiene – routinely just as they brush their teeth. Early detection is key and is consistent with traditional communicable disease control methods.
- B. Have parents machine wash all potentially exposed clothes, sheets, etc. in hot water, and dry them in a hot dryer.
- C. Any item that can't be washed or dry-cleaned can be vacuumed. Recommend vacuuming as the safest and most effective alternative to spraying.
- D. Some professionals have suggested "bagging" items in plastic bags. Discourage bagging and encourage vacuuming. Having head lice can be traumatic, especially for children. Often it's their favorite stuffed animal, or blanket that gets bagged, just when they need it most. Parents should know to save their energy for that which benefits them the most: attention to the scalp and hair for early detection along with complete lice and nit removal.
- E. Do not recommend retreatment based on the patient's scalp being "itchy." Remember that prior treatment itself can cause the scalp to itch and this symptom does not validate an infestation.
- F. Inquire about daily screening and thorough nit removal. Remind the patient that an ongoing infestation is predictable without these measures.

### 5. Prevent new outbreaks.

- A. Encourage parents to notify their child's school, camp, childcare provider, and neighborhood parents regarding possible outbreaks. Parents should check for head lice on a regular basis. Remember that head lice affect all social groups. Reporting should be encouraged.
- B. Advise **AGAINST** treating anybody who is not infested. Do not recommend prophylactic treatment.

**Public Health Aspects: Minimize community outbreaks by taking a leadership role in lice prevention in your community.**

#### 1. Minimize Community Outbreaks

- A. Inform your community that you want to be part of a community approach – that you are available for educational information as well as advice about treatment and head lice management.



- B. You may choose to provide in-service training for local teachers, YMCA staff, camp directors, childcare personnel, etc.
- C. Support the important step of reporting outbreaks, treatment failures, and adverse reactions to the NPA's National Reporting Registry, local health departments, and school officials. Remember that early reporting can mobilize communities to do preventive screening.
- D. Encourage routine screening, early detection, and complete removal of both lice and nits.


**2. Take a leadership role in lice prevention in your community.**

- A. Teach others how to minimize outbreaks. Because most head lice information comes from product advertising, you should look to the National Pediculosis Association® for impartial resources and materials.
- B. Encourage everyone to join the NPA's Back-To-School "National Pediculosis Prevention Month" activities that continue throughout the year.

**3. Advise others to exercise caution in selecting and using products for treatment.** Overuse of anti-lice pesticides has caused insect resistance similar to the current situation with some bacteria and antibiotics.

**4. Update physicians about possible new treatments and issues related to Pediculosis.**

Head lice are often perceived as "unglamorous" and unworthy of serious attention. As a result, there is conflicting information and no nationally standardized approach. Encourage everyone to get the facts and CHECK A HEAD.™

<p><b>GUIDE DEVELOPED BY:</b> National Pediculosis Association 50 Kearney Road Needham, MA 02494 (781) 449-NITS <a href="http://www.headlice.org">www.headlice.org</a>  in cooperation with Pharmacist's Letter®</p>	 <p>Click here for printable versions of this and other NPA publications</p>
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## Lindane Education And Research Network

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Replacing one poison with another only continues to degrade the quality of all life.

## Lindane Status

## Laundering pesticide contaminated clothing

Common Name: Lindane  
CAS Number: 58-89-9  
DOT Number: NA 2761  
Date: July, 1988  
-----

## HAZARD SUMMARY

- \* Lindane can affect you when breathed in and by passing through your skin.
- \* Lindane should be handled as a CARCINOGEN WITH EXTREME CAUTION.
- \* Overexposure can cause irritability, restlessness, anxiety, poor appetite, and headache. Higher levels can also cause muscle twitching, convulsion (fits) and even death.
- \* It also may damage the developing fetus and reduce fertility in females.
- \* Repeated overexposure may cause liver damage.

## IDENTIFICATION

Lindane is a colorless solid with a musty odor. It is an organochlorine insecticide.

## REASON FOR CITATION

- \* Lindane is on the Hazardous Substance List because it is regulated by OSHA and cited by ACGIH, DOT, NTP, DEP and EPA.
- \* This chemical is on the Special Health Hazard Substance List because it is a CARCINOGEN.
- \* Definitions are attached.

## HOW TO DETERMINE IF YOU ARE BEING EXPOSED

- \* Exposure to hazardous substances should be routinely evaluated. This may include collecting personal and area air samples. You can obtain copies of sampling results from your employer. You have a legal right to this information under OSHA 1910.20.
- \* If you think you are experiencing any work related health problems, see a doctor trained to recognize occupational diseases. Take this Fact Sheet with you.

## WORKPLACE EXPOSURE LIMITS

OSHA: The legal airborne permissible exposure limit (PEL) is 0.5 mg/m3 averaged over an 8 hour workshift.  
ACGIH: The recommended airborne exposure limit is 0.5 mg/m3 averaged over an 8 hour workshift.

- \* Lindane may be a CARCINOGEN in humans. There may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level.

## WAYS OF REDUCING EXPOSURE

- \* Where possible, enclose operations and use local exhaust ventilation at the site of chemical release. If local exhaust ventilation or enclosure is not used, respirators should be worn.
- \* Wear protective work clothing.
- \* Wash thoroughly immediately after exposure to Lindane and at the end of the workshift.
- \* Post hazard and warning information in the work area. In addition, as part of an ongoing education and training effort, communicate all information on the health and safety hazards of Lindane to potentially exposed workers.

This Fact Sheet is a summary source of information of all potential and most severe health hazards that may result from exposure.

Duration of exposure, concentration of the substance and other factors will affect your susceptibility to any of the potential effects described below.

-----

#### HEALTH HAZARD INFORMATION

##### Acute Health Effects

The following acute (short term) health effects may occur immediately or shortly after exposure to Lindane:

- \* Overexposure by skin contact or breathing can cause restlessness, insomnia, anxiety, irritability, poor appetite and/or headache. Higher exposures can also cause muscle twitching, seizures, convulsions or "fits" and even death.

##### Chronic Health Effects

The following chronic (long term) health effects can occur at some time after exposure to Lindane and can last for months or years:

##### Cancer Hazard

- \* Lindane may be a CARCINOGEN in humans since it has been shown to cause liver, lung, endocrine glands and other types of cancer in animals.
- \* There is limited evidence that Lindane is associated with leukemia in humans.
- \* Many scientists believe there is no safe level of exposure to a carcinogen. Such substances may also have the potential for causing reproductive damage in humans.

##### Reproductive Hazard

- \* Lindane may damage the developing fetus.
- \* Lindane may decrease fertility in females.

##### Other Long Term Effects

- \* Repeated overexposure may damage the liver or cause damage to the nerves of the arms and legs, possibly with weakness and poor coordination.
- \* Exposure may also cause a serious drop in the blood cell count (aplastic anemia) or in the white blood cell count (agranulocytopenia).

#### MEDICAL TESTING

For those with frequent or potentially high exposure (half the TLV or greater, or significant skin contact), the following are recommended before beginning work and at regular times after that:

- \* Exam of the nervous system.
- \* Complete blood count (CBC).

If symptoms develop or overexposure is suspected, the following may also be useful:

- \* Blood test for Lindane (may not be accurate longer than 1 week after last exposure).
- \* Liver function tests.

Any evaluation should include a careful history of past and present symptoms with an exam. Medical tests that look for damage already done are not a substitute for controlling exposure.

Request copies of your medical testing. You have a legal right to this information under OSHA 1910.20.

#### WORKPLACE CONTROLS AND PRACTICES

Unless a less toxic chemical can be substituted for a hazardous substance, ENGINEERING CONTROLS are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

In evaluating the controls present in your workplace, consider: (1) how hazardous the substance is, (2) how much of the substance is

released into the workplace and (3) whether harmful skin or eye contact could occur. Special controls should be in place for highly toxic chemicals or when significant skin, eye, or breathing exposures are possible.

In addition, the following controls are recommended:

- \* Where possible, automatically transfer Lindane from drums or other storage containers to process containers.
- \* Specific engineering controls are recommended for this chemical by NIOSH. Refer to the NIOSH criteria document: "Occupational exposure during the Manufacture and Formulation of Pesticides #78 174".

Good WORK PRACTICES can help to reduce hazardous exposures. The following work practices are recommended:

- \* Workers whose clothing has been contaminated by Lindane should change into clean clothing promptly.
- \* Do not take contaminated work clothes home. Family members could be exposed.
- \* Contaminated work clothes should be laundered by individuals who have been informed of the hazards of exposure to Lindane.
- \* If there is the possibility of skin exposure, emergency shower facilities should be provided.
- \* On skin contact with Lindane, immediately wash or shower to remove the chemical. At the end of the workshift, wash any areas of the body that may have contacted Lindane, whether or not known skin contact has occurred.
- \* Do not eat, smoke, or drink where Lindane is handled, processed, or stored, since the chemical can be swallowed. Wash hands carefully before eating or smoking.
- \* Use a vacuum or a wet method to reduce dust during cleanup. DO NOT DRY SWEEP.
- \* When vacuuming, a high efficiency particulate absolute (HEPA) filter should be used, not a standard shop vacuum.

#### PERSONAL PROTECTIVE EQUIPMENT

WORKPLACE CONTROLS ARE BETTER THAN PERSONAL PROTECTIVE EQUIPMENT. However, for some jobs (such as outside work, confined space entry, jobs done only once in a while, or jobs done while workplace controls are being installed), personal protective equipment may be appropriate.

The following recommendations are only guidelines and may not apply to every situation.

#### Clothing

- \* Avoid skin contact with Lindane. Wear protective gloves and clothing. Safety equipment suppliers/manufacturers can provide recommendations on the most protective glove/clothing material for your operation.
- \* All protective clothing (suits, gloves, footwear, headgear) should be clean, available each day, and put on before work.

#### Eye Protection

- \* Wear dust proof goggles and face shield when working with powders or dust, unless full facepiece respiratory protection is worn.

#### Respiratory Protection

IMPROPER USE OF RESPIRATORS IS DANGEROUS. Such equipment should only be used if the employer has a written program that takes into account workplace conditions, requirements for worker training, respirator fit testing and medical exams, as described in OSHA 1910.134.

- \* Where the potential exists for exposures over 0.5 mg/m<sup>3</sup>, use a MSHA/NIOSH approved supplied air respirator with a full facepiece operated in the positive pressure mode or with a full facepiece, hood, or helmet in the continuous flow mode, or use a MSHA/NIOSH approved self contained breathing apparatus with a full facepiece operated in pressure demand or other positive pressure mode.
- \* Exposure to 1000 mg/m<sup>3</sup> is immediately dangerous to life and health. If the possibility of exposures above 1000 mg/m<sup>3</sup>

exists, use a MSHA/NIOSH approved self contained breathing apparatus with a full facepiece operated in continuous flow or other positive pressure mode.

Common Name: Lindane  
DOT Number: NA 2761  
DOT Emergency Guide code: 55  
CAS Number: 58-89-9

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Hazard rating  NJ DOH          NFPA
FLAMMABILITY   Not Found      Not Rated
REACTIVITY     Not Found      Not Rated
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#### POISONOUS GASES ARE PRODUCED IN FIRE

Hazard Rating Key: 0=minimal; 1=slight; 2=moderate; 3=serious;  
4=severe

#### FIRE HAZARDS

- \* Use dry chemical, CO2, water spray, or foam extinguishers.
- \* POISONOUS GASES ARE PRODUCED IN FIRE, including Phosgene and Hydrogen Chloride.
- \* If employees are expected to fight fires, they must be trained and equipped as stated in OSHA 1910.156.

#### SPILLS AND EMERGENCIES

If Lindane is spilled, take the following steps:

- \* Restrict persons not wearing protective equipment from area of spill until cleanup is complete.
- \* Collect powdered material in the most convenient and safe manner and deposit in sealed containers.
- \* It may be necessary to contain and dispose of Lindane as a HAZARDOUS WASTE. Contact your state Environmental Program for specific recommendations.

=====

FOR LARGE SPILLS AND FIRES immediately call your fire department.

=====

#### HANDLING AND STORAGE

- \* Prior to working with Lindane you should be trained on its proper handling and storage.
- \* Lindane must be stored to avoid contact with STRONG ALKALIS and POWDERED METALS since violent reactions occur.
- \* Store in tightly closed containers in a cool, well ventilated area.

#### FIRST AID POISON INFORMATION

##### Eye Contact

- \* Immediately flush with large amounts of water for at least 15 minutes, occasionally lifting upper and lower lids.

##### Skin Contact

- \* Quickly remove contaminated clothing. Immediately wash contaminated skin with large amounts of soap and water. Shampoo hair thoroughly if contaminated.

##### Breathing

- \* Remove the person from exposure.
- \* Begin rescue breathing if breathing has stopped and CPR if heart action has stopped.
- \* Transfer promptly to a medical facility.

#### PHYSICAL DATA

Water Solubility: Insoluble

#### OTHER COMMONLY USED NAMES

## Chemical Name:

Cyclohexane, 1,2,3,4,5,6 Hexachloro , (1alpha, 2alpha, 3beta, 4alpha, 5alpha, 6beta)

## Other Names and Formulations:

Benzene Hexachloride; Kwell R; gamma BHC Benhexachlor.

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## ECOLOGICAL INFORMATION

Lindane is an organochlorine insecticide which has been used against insects in a wide range of applications. It has been used to treat animals, buildings, humans for ectoparasites; clothes; water for mosquitoes; living plants, seeds, and soils. It may enter the environment from industrial discharges, insecticide applications, or spills.

## ACUTE (SHORT-TERM) ECOLOGICAL EFFECTS

Acute toxic effects may include the death of animals, birds, or fish, and death or low growth rate in plants. Acute effects are seen two to four days after animals or plants come in contact with a toxic chemical substance.

Lindane has high acute toxicity to aquatic life and to birds. Insufficient data are available to evaluate or predict the short-term effects of Lindane to plants or land animals.

## CHRONIC (LONG-TERM) ECOLOGICAL EFFECTS

Chronic toxic effects may include shortened lifespan, reproductive problems, lower fertility, and changes in appearance or behavior. Chronic effects can be seen long after first exposure(s) to a toxic chemical.

Lindane has high chronic toxicity to aquatic life. Insufficient data are available to evaluate or predict the long-term effects of Lindane to plants, birds or land animals.

## WATER SOLUBILITY

Lindane is moderately soluble in water. Concentrations of between 1 to 1,000 milligrams will mix with a liter of water.

## DISTRIBUTION AND PERSISTENCE IN THE ENVIRONMENT

Lindane is moderately persistent in water, with a half-life of between 20 to 200 days. The half-life of a pollutant is the amount of time it takes for one-half of the chemical to be degraded. About 52.3% of Lindane will eventually end up in water; about 23.4% will end up in terrestrial soil; about 22% will end up in aquatic sediments; and about 2.3% will end up in air.

## BIOACCUMULATION IN AQUATIC ORGANISMS

Some substances increase in concentration, or bioaccumulate, in living organisms as they breathe contaminated air, drink contaminated water, or eat contaminated food. These chemicals can become concentrated in the tissues and internal organs of animals and humans.

The concentration of Lindane found in fish tissues is expected to be somewhat higher than the average concentration of Lindane in the water from which the fish was taken.

SUPPORT DOCUMENT: AQUIRE Database, ERL-Duluth, U.S. EPA.  
<http://chppm-www.apgea.army.mil/ento/facts/lindane.htm>

**LINDANE STATUS**

We have received many inquiries recently on the status of the 1% lindane. As a result, we are printing the message which was sent out regarding the turn-in of the lindane stocks.

PRIORITY/ROUTINE  
P R 141800Z APR 94  
FM DGSC RICHMOND VA//STAC//QED//

UNCLAS  
SUBJECT: AFPMB NOTICE ON INSECTICIDE, LINDANE DUSTS

1. Reference: Armed Forces Pest Management Board/AFPMB/letter, 25 March 1994/Not to all/.
2. Addressees are responsible for dissemination of this message to all lateral and subordinate units, maintenance activities, elements or foreign users affected or concerned. Include DGSC, Richmond, VA/STAC as info addressee on all retransmitted messages. This is a coordinated DGSC-S/Q message.
3. All service inventories of NSN 6840-00-242-4217, 1 percent lindane in 2 oz containers shall be turned in to the local DRMO for disposal. NSN was cancelled 1 January 1993. No DOD requirements exist. DGSC does not have this NSN in our inventory.
4. All DLA and service inventories of NSN 6840-00-242-4219, 1 percent lindane in 25 lb. drum also shall be turned in to the local DRMO for disposal. Action has been initiated to cancel NSN without replacement.
5. The rationale for these actions is threefold. First, DOD is changing the treatment procedures for mass delousing: The indiscriminate application of lindane, without first determining whether individuals are infested with lice, is not a sound pest management practice. Second, although lindane is currently registered by the environmental protection agency, it is a very persistent pesticide in the environment and it is categorized as a "B2" carcinogen/probable carcinogen based on animal studies. Finally, discontinuing use of lindane is consistent with pesticide risk reduction goals established by the Defense Environmental Security Council.
6. These actions are mandatory. DOD Directive 4150.7 and DOD Directive 6050-10 provides the AFPMB the authority for this turn in and disposal.
7. If you have questions concerning these actions, please contact Mr. Clifford Myers, DGSC-STAC, Chemist, DSN 695-3995 or 804-279-3995 or LtCol Bob McKenna at DSN 291-5191 or 301-427-5191.

<http://chppm-www.apgea.army.mil/ento/bulsep94.htm>

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**LAUNDERING PESTICIDE CONTAMINATED CLOTHING**

The following information was printed in the *Pesticide Control Report*, published by the New Jersey Department of Environmental Protection and Energy. We think the information is worth repeating here in our Bulletin.

Pesticides are necessary tools in pest management but, like any other tool, they can be dangerous when mishandled or when accidents occur. Drift, accidental spills, or carelessness can cause pesticide contact with the user or his/her clothing. This clothing is then considered contaminated.

If pesticides get on your clothing, change clothes as soon as possible. Don't wait until the end of the day or until you've finished the job. If you continue to wear pesticide-contaminated clothing, the pesticide residue could be absorbed through your skin into your bloodstream, where it could cause serious health problems.

When you handle pesticide-contaminated clothing, always wear unlined waterproof gloves. Also, thoroughly clean washers after laundering contaminated clothing. This means that after every load of pesticide-contaminated clothing, run the machine through a complete cycle with hot water and detergent only. This simple step requires a little extra time, but studies show that it will help to prevent contaminating future wash loads.

Before bringing contaminated clothing into the shop, decide whether you can launder it thoroughly or if you should discard the clothing. Discard clothing saturated with highly toxic, undiluted pesticide formulations, such as emulsifiable concentrates. Dispose of the clothing by placing it in a plastic bag, closing the bag tightly, and disposing of it in an approved sanitary landfill.



Never take pesticide contaminated clothing home to be laundered in the family washing machine. Launder **ONLY** clothing contaminated with water-soluble low-toxicity pesticides. Discard contaminated leather items, such as watchbands, gloves, and boots. You cannot decontaminate leather items. When these items are worn again and become wet, the pesticide residue could become active again and could cause a rash or sores.

Never handle pesticide-contaminated clothing with your bare hands. To avoid dermal exposure, always wear unlined waterproof gloves. Wash the gloves off thoroughly before removing them and use them for this purpose only. Test gloves for leaks by filling them with water and gently squeezing. Discard gloves as soon as they develop a leak.

On a daily basis, launder clothing worn during pesticide applications. Pesticide residues in clothing can build up and become more difficult to remove.

If you must store contaminated clothing before laundering, hang them in an area not used by you or your co-workers, and where air movement will help dissipate or remove some of the pesticide.

Because pesticide residues could be transferred to other clothing in the wash load, always launder contaminated clothes separately. This will help prevent contaminating clothing worn by other workers.

Research at North Dakota State University shows that prerinsing is a very important step. It not only reduces the amount of pesticide in contaminated clothing before laundering, but it also minimizes contamination of laundry equipment, which could then contaminate clothing in future wash loads.

Empty pockets and cuffs of any pesticide granules outdoors, and discard them safely. In a bucket or pail, prerinse contaminated clothing in hot or warm water at least twice. Because pesticide formulations usually contain some detergent, it is not necessary to add detergents when prerinsing. Dispose of prerinse water as a pesticide-related waste.

Launder only a few (three or four) contaminated garments at a time. Use a full water level to thoroughly flush the pesticide from the fabric. This also decreases the possibility of redepositing pesticide residue on fabric.

Wash together only garments contaminated with the same pesticide. Hot (140 F) water is most effective in removing pesticide residues from clothing. Cold water is least effective.

Use a normal 12-minute wash cycle. Select detergents according to the type of pesticide that contaminated the clothing. Research has shown that heavy-duty detergents, such as Era and Wisk, are more effective than other detergents in removing emulsifiable concentrate pesticide formulations. Emulsifiable concentrate formulations are oil-based and heavy-duty liquid detergents are known for their oil-removing ability. Research shows that granular detergents such as Tide, Oxydol, and Cheer, are effective in removing water-soluble pesticides. If it is not possible to determine the pesticide formulation, use a heavy-duty detergent.

Results to date show that neither bleach nor ammonia aid in the removal of pesticide residues. You may wish to use them to remove other types of soil or stains, but never mix them together. In combination, they react to form a fatal chlorine gas.

For more effective removal of pesticide residue, repeat the wash cycle several times.

Line dry laundered garments outdoors. This eliminates the possibility of pesticide residue collecting in the dryer where it could contaminate clothes in future loads. Sunlight and air movement help to decontaminate any pesticide residue not removed during laundering.

If you must use a clothes dryer, wipe the dryer with a damp cloth after each load, and then discard the cloth.

Laundering pesticide-contaminated clothing correctly must be an important activity of any pest management operation. Now would be a good time to evaluate how your pest management activity launders clothing contaminated with pesticides.

<http://chppm-www.apgea.army.mil/ento/bulsep94.htm>

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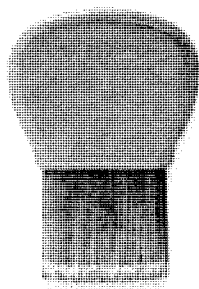
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## The LiceMeister® Comb

The LiceMeister comb is the Gold Standard  
imposters can't match!

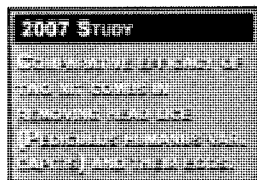
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for stores selling  
the LiceMeister  
(US & Canada)

How to use  
watch video



Critter Cards



### The LiceMeister® Comb



The only comb endorsed by the National Pediculosis Association.®  
The "Gold Standard" medical device packaged with combing instructions, a convenient cleaning tool

And bonus:

NPA's Critter Card to show you what to look for and know how to see the difference between lice eggs (nits) and normal hair debris.

What Makes the LiceMeister the Best Lice and Nit Removal Comb? [Find Out](#)

### ORDER NOW

#### Order Online:

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**1-866-323-5465 ext 7984**

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### The Fight Against Head Lice

When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school, lice and nit free!

*The NPA is a non-profit organization. Proceeds from the LiceMeister comb help support the NPA's programs of education, prevention and research.*

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*National Pediculosis Association<sup>®</sup>, Inc.*

## Signs and Symptoms of Lindane Exposure

**Effects can be immediate or delayed. Onset of some symptoms may be subtle.  
May include one or combination of the following manifestations:**

acute renal failure with azotemia,

ADD/ADHD

anxiety,

autism,

atonia,

agranulocytosis,

aplastic anemia,

anorexia,

apprehensive mental state,

behavior-mood disturbances,

bullae,

cancer,

cardiac arrhythmias,

clumsiness,

coma,

confusion,

conjunctivitis,

convulsions,

cough,

cyanosis,

death,

dermatitis,

diaphoresis,

diarrhea,

disorientation,

dizziness,

dyspnea,

emotional lability,

excitement,

excessive hair growth,

fast heartbeat,

fatigue,

fever,

giddiness,

grinding teeth,

headaches,

heart palpitations,

hematuria,

Signs & Symptoms of Lindane Exposure

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hyperirritability,  
hypersensitivity,  
incoordination,  
kidney damage,  
liver damage,  
liver enlargement,  
loss of appetite,  
mania,  
mental retardation,  
muscle cramps, muscle spasms, muscle tremors,  
nausea,  
nervousness,  
oliguria,  
pallor,  
paraesthesia,  
paresis,  
paresthesia,  
porphyria,  
proteinuria,  
pulmonary edema,  
restlessness,  
respiratory failure,  
seizures,  
shaking,  
sweating,  
tachycardia,  
tearing,  
thirst,  
trouble breathing,  
trouble swallowing,  
urticaria,  
vertigo,  
vomiting,  
weakness,  
wheezing,  
**elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes.**

**ACETONE:**

dizziness,  
light-headedness,  
fainting,  
headaches,  
irritates eyes, nose, & throat,  
unconsciousness  
dermatitis,  
liver & kidney damage

The signs and symptoms of exposure listed here are compiled from all the data contained within the links of this site.

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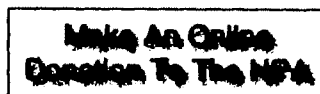
<http://www.headlice.org/lindane/health/symptoms.htm>

1/8/2007

## Signs & Symptoms of Lindane Exposure

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### Lindane Regulatory Status

[Illinois Bans Lindane](#)

[California Law](#)



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[Lindane Ban Campaign](#)

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[Alaska](#)[Illinois](#)[Indiana](#)[Maine](#)[New York](#)**Illinois Banned Lindane****Ban Lindane Now!**[Lindane in Illinois](#)[Articles & Resources](#)[Discussion](#)[Google Search](#)[Lindane Petition](#)

April 8, 2005

[Full Text](#)

Amends the Illinois Food, Drug, and Cosmetic Act. Provides that no person shall sell, deliver, offer for sale, hold for sale, give away, use, or prescribe any product used for the treatment of lice or scabies in human beings that contains the pesticide chemical lindane. Effective January 1, 2006.

<http://www.ilga.gov/legislation/BillStatus.asp?DocTypeID=HB&DocNum=1362&GAID=8&SessionID=50&LegID=16128>

**Illinois:** Progressive lobbyist Dan Johnson-Weinberger is spearheading an effort to pass state legislation banning lindane in Illinois. For more information contact Dan Johnson-Weinberger, [midwestdemocracy@yahoo.com](mailto:midwestdemocracy@yahoo.com)

- IL draft legislation
- IL PANAlert to State Representatives

**Cancer Prevention Coalition**

<http://www.preventcancer.com/patients/children/lindane.htm>

**Google Illinois Lindane****Google News Search Lindane**

<http://www.panna.org/campaigns/lindaneState.html>



Last modified:  
05/03/2005 07:25 AM

<http://www.headlice.org/lindane/petition/illinois.htm>

2/6/2007

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## Prescriptions For Harm

### When Chemical Warfare Against Lice Becomes Chemical Warfare Against Kids

*The National Pediculosis Association says FDA's latest warnings fail. The FDA's warning, although an important action, is ambiguous and fails to protect the public. Their black box (representing the most stringent of warnings for a product) is negated by the recommendation to use Lindane as a second-line therapy or after other products have failed. The NPA urges FDA to ban Lindane.*

April 1, 2003 - On March 28, 2003, the U.S. Food and Drug Administration (FDA) announced new warnings on prescriptions for children containing the chemical Lindane, a topical formulation used to treat head lice and scabies. The warning emphasizes that these products should be used "with caution on patients who weigh less than about 110 pounds."

This comes after the FDA's earliest warning in 1976 of seizures associated with Lindane and its more recent admonition in 1996 warning consumers of severe skin inflammation. At that time, the label was already required to warn of potential neurological side effects.

Lindane, a bio-accumulative and toxic chemical was used as a chemical weapon during World War I. It is used for medical research to induce seizures in rats and the Agency for Toxic Substances and Disease Registry has prioritized Lindane as 33rd on its list of 275 hazardous substances.

It is a known risk to humans and, when utilized as a shampoo or lotion treatment for lice or scabies, is documented as a serious contaminant of water via residential use of public sewers. A single treatment for head lice or scabies with Lindane pollutes 6 million gallons of water.

The state of California banned Lindane totally in 2001 following documentation of Lindane pollution in LA County's water supply and investigations continue regarding pollution from other lice treatment pesticides including Permethrin and Malathion, according to Ann Heil, Senior Engineer for the Sanitation District of Los Angeles County.

The National Pediculosis Association (NPA), Consumers Union and Ralph Nader's Public Citizen group filed petitions with the FDA to ban Lindane and testified before the FDA to this effect in 1983, 1984, 1985, 1993, and 1995. Many other health and environmental organizations such as the National Resources Defense Council have joined the effort that continues to this day.

The NPA, a non-profit organization incorporated in 1983 to protect children and their families from misuse and abuse of pediculicides and scabicides, submitted several hundred Lindane and other pesticide treatment related adverse event reports to MedWatch (the FDA's Safety Information and Adverse Event Reporting Program) in 1995.

This prompted the FDA's 1996 warning about misuse. However, reports to the NPA reflect that "normal" use of these products is misuse,

#### CONTACT INFORMATION

**Jane Cotter**  
National Pediculosis  
Assoc.  
781-449-6487 x109

#### ATTACHED FILES

**NPA Alert!**  
Alert to Parents and Health  
Professionals

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making chemical treatments for head lice a constant and predictable health risk.

Opportunities for inappropriate use of over-the-counter and prescription treatments designed to kill lice or remove nits are common. Products with scientifically proven lice resistance continue to be vigorously marketed to the public and recommended through industry-driven guidelines such as those recently adopted by the American Academy of Pediatrics.

Over 95% of lice products currently available on the drug store shelf are known to be less than 100% effective at best, and, in many cases, totally ineffective given documented lice resistance.

At the expense of prudent prevention measures and safer choices, parents are regrettably directed to seek prescription pesticides such as Lindane or Malathion as a follow-up remedy to ineffective over-the-counter pesticide shampoos, cremes and lotions.

To avoid potential harm, the NPA alerts parents via its website – [www.headlice.org](http://www.headlice.org) – that "Pesticide shampoos, cremes and lotions are not to be used repeatedly, in conjunction with, or as a follow-up to other chemical formulations."

The alert also states: "New industry-driven guidelines direct parents and health professionals to over-the-counter pesticide products already documented to be less than 100% effective at best, or with documented lice resistance to them. When these treatments fail, the guidelines unfortunately recommend the prescription pesticides Malathion and Lindane. There are health risks inherent with the use of pesticides on children and these risks increase dramatically when you follow one chemical treatment with another."

The NPA advises parents to "Discontinue the use of any treatment at the earliest sign of failure and to avoid using other chemicals. Manual removal is the best option whenever possible, especially when treatment products have failed."

The NPA has, since its inception, informed parents and health professionals about the risks of pesticides for lice and scabies with warnings to avoid Lindane entirely. The NPA emphasizes education in advance of outbreaks, and promotes routine screening, early detection and manual removal by combing as the safe, non-chemical alternative for lice. The NPA accomplishes and supports its mission of education, research and prevention by providing screening and combing tools and educational resources.

The FDA's warning, although an important action, is ambiguous and fails to protect the public. Their black box (representing the most stringent of warnings for a product) is negated by the recommendation to use Lindane as a second-line therapy or after other products have failed.

This ignores the cumulative and unpredictable combined effects of exposures to numerous other pesticides for lice and renders children more susceptible to harm from Lindane's potentially adverse effects. Such an approach is illogical and makes for double jeopardy.

We cannot expect, nor can we hope, to successfully control Pediculosis and protect children's health by reliance on unsafe, ineffective treatments or by replacing one poison with another.

Lindane's continued availability for use on children and their families in spite of what is known about the hazards of this chemical, and allowing products with documented lice resistance to remain available to consumers, contradicts FDA's mandate to provide for the safety of the public.

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## Chemical Treatments for Head Lice are Not Created Equal

Chemical treatments for head lice are not created equal. And while all of the commercially available products are pesticides, some are more toxic than others. The prescriptions for lice and scabies that contain the chemical lindane are among the most risky. One should also know that none of the products are 100% effective... even though the packaging may make you think otherwise. Descriptions of pesticides derived from the chrysanthemum flower are among the misleading. Manufactures never tell you about the synergists and solvents that are mixed with the supposedly naturally-derived pesticide ingredient. If it kills a bug like "they" say it should then it is a pesticide by definition.

Chemical treatments have their place for certain individuals for specific reasons. Yet there are others who should never be exposed to them. This is especially true if the person involved is pregnant, nursing, has allergies, asthma, epilepsy, open wounds, or pre-existing medical conditions. Children who have been treated repeatedly for head lice (or scabies) or exposed to lice sprays (or flea bombs) may be more at risk of adverse events with additional chemical exposures. Seizures, behavioral changes, attention deficit disorders, cancer, skin diseases, and even death have been reported to the National Pediculosis Association's registry by people who have used chemical treatments to get rid of head lice or scabies.



There's tons of misinformation out there. Don't let your family fall victim to it. If you choose to use a chemical treatment follow the directions that come with the treatment.



- Don't use shower caps and never leave the product on longer than directed.
- Don't use a prescription product containing the pesticide LINDANE.
- Don't use a chemical treatment on or near the eyes.
- Don't use a head lice treatment on a baby.
- Don't use lice sprays.
- Don't buy products that are packaged with Lice Sprays.
- Don't treat individuals who are not infested.
- Don't use treatments to prevent head lice.

Head Lice management is much more than the often-perceived issue of unwanted bugs and most available treatment remedy. Endemically positioned among children, head lice have begun a cycle of responses which in some cases become more worrisome than the critters themselves.

### Alert!

Following one treatment with another is ill advised... click here for details!

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Information**EPA to Assess The Risks of Lindane EPA Docket Control #0PP-34239**

We Can't Wait Another 15 Years!

BOSTON, Oct. 4 /PRNewswire/ -- The Environmental Protection Agency (EPA) provides an opportunity for public comment on the risks of Lindane once every 15 years. This deadline is October 29, 2001. The National Pediculosis Association and the Los Angeles County Sanitation Department encourage the public to contact the EPA on this matter.

Lindane, a bio-accumulative and toxic chemical, is a known health risk to humans, especially children, and its adverse affects are far reaching from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death. Lindane pollutes 6 million gallons of water with a single treatment for head lice or scabies. Rinsing into household sinks and showers puts Lindane through public sewers and into water supplies, which, at the most basic level, violates regulations for residential hazardous waste disposal.

Lindane is toxic and an unnecessary risk to all forms of life and for this reason has been banned in the state of California. The EPA needs to hear from the public in order to amend the rules governing their assessment of Lindane for the rest of the country. The EPA has scientific documentation of the environmental risks of Lindane when used as a human lice and scabies treatment. However, due to the separation of power between the EPA and FDA (Food and Drug Administration), the EPA is not allowed to include this data in its Lindane Risk Assessment. **THIS MUST CHANGE NOW!** We cannot afford to wait another 15 years for government agencies to fully cooperate on this urgent matter affecting the public health and environment.

We can't remove every potentially harmful chemical exposure in our lives. Therefore it is vital that we remove those that we can. Lindane must go and we must remain vigilant not to replace this poison with another.

A prepared sample letter for you to submit directly to the EPA is available at <http://www.headlice.org/> or write to the EPA including docket number 0PP-34239.

Public Information and Records Integrity Branch (PIRIB)  
Information Resources and Services Division (7502C)  
Office of Pesticide Programs (OPP)  
Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

The National Pediculosis Association is a Non Profit organization serving the public since 1983 with a mission to protect children from unnecessary exposure to pesticides used to treat lice and scabies. The NPA along with LA County Sanitation Department recently received the prestigious 2001 Most Valuable Pollution Prevention Award for the nation. <http://www.headlice.org/news/headlines/npnr.htm>

SOURCE The National Pediculosis Association

Web Site: <http://www.headlice.org/>

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## Head lice shampoo 'linked to leukaemia'

by EMILY COOK, Daily Mail 08:35am 17th January 2006

Using chemical shampoos to get rid of head lice could almost double the risk of children developing leukaemia, scientists have claimed.

Exposure to other insecticides while in the womb or as a child could also double the risk of contracting the cancer, they said.

The findings will fuel concerns about the increasing incidence of childhood leukaemia in Britain. Around 500 youngsters under 15 are diagnosed with the illness each year.

It kills more children than any other disease in the UK and cases among under-fives have risen by more than 50 per cent in 40 years.

The study, by the French research group INSERM, looked at 280 children newly diagnosed with acute leukaemia and a further 288 children matched for sex and age who did not have the disease.

The mothers of the children, who came from four French cities, were interviewed about their use of insecticidal head lice shampoos and of pesticides and fungicides in the home and garden. They were also asked whether they used the chemicals during and after pregnancy.

Based on what the mothers said, scientists concluded that using insecticidal shampoos could almost double the risk of developing leukaemia.

They also found the risk of developing acute leukaemia was almost twice as likely in children whose mothers said they had used insecticides in the home while pregnant and long after birth.

Dr Florence Menegaux, who led the study which is published in the journal Occupational and Environmental Medicine, said: "The findings reinforce the hypothesis that household pesticides may play a role in the origin of childhood acute leukaemia.

"At this stage no specific product can be singled out and a causal link remains questionable. However, the consistency of our results and the results from previous studies suggest that it may be opportune to consider preventative action."

The research did not specify any of the lice shampoo brands used by the children, but cited ingredients such as malathion, pyrethroid and lindane which are often in such products.

The most popular products available over the counter include Lyclear (containing permethrin - a pyrethroid) and Derbac-M, (containing malathion).

The UK market for head lice products is worth £15.6million per year. Special 'bug busting' combs and organic treatments are also used.

### 'Weak evidence'

The Leukaemia Research Fund said: "This is a very small study and the evidence is very weak.

"However this does not mean there are no harmful consequences. More research is needed."

The Medicines and Healthcare products Regulatory Agency, the Government's drug safety watchdog, said: "We have tested the safety of current head lice lotions and shampoos available. Tests show that absorption into the body is quite minimal and we would not advise people to stop using them."

A spokesman for Chefaro UK, which manufactures Lyclear, said: "The statistical probability of there being a link appears to be very low. Lyclear Creme Rinse has been tested for toxicity, and absorption rates through the skin were found to be negligible."

[http://www.dailymail.co.uk/pages/live/articles/health/healthmain.html?  
in\\_article\\_id=374306&in\\_page\\_id=1774&in\\_a\\_source=](http://www.dailymail.co.uk/pages/live/articles/health/healthmain.html?in_article_id=374306&in_page_id=1774&in_a_source=)

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05/25	Hair hygiene thru Mediker
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05/02	Head Lice Win Again! Los Angeles County School District SaysYes to Lice Eggs (Nits)

04/28	<b>People recommend pesticide treatments for head lice as though it is the only poison exposure in a child's life.</b>
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01/23	<b>EPA criteria for testing pesticides on human subjects</b> Read carefully
01/23	<b>The Human Louse and Disease</b> Recent studies support the critical need for preparedness and lice prevention.
01/17	<b>Lindane linked to Leukemia in children</b> Today's news item, but known for decades!

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HeadLice.Org<sup>SM</sup>

HeadLice.Org Hot Spots:

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## Your Reports Help Us Help You!

The Registry and its reports are needed to identify problems as early as possible. The NPA can then submit its findings and seek appropriate assistance from experts and governmental agencies including the Food and Drug Administration (FDA). Please click here to report:

- **Food and Drug Administration (FDA) MedWatch Program**

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions and problems with medical products, such as drugs and medical devices. The medical community and its physicians cannot appreciate the hazards of lindane, lice sprays, and other pesticidal treatment products until adverse reactions and treatment failures are identified and reported. If you have noticed an adverse reaction or a treatment failure, please fill out this form.

- **Adverse Reactions for Lice or Scabies Products**

Any incident where the use of a product is suspected to have resulted in harm to the patient or the person applying treatment. It is NOT necessary to be certain of a cause/effect relationship between the adverse event and the use of the product(s) in question. Suspicion of an association is sufficient.

- **Treatment Failures for Lice or Scabies Products**

Any report regarding the quality, performance, or safety of any product. Product problems include, but are not limited to, such concerns as: questionable effectiveness, therapeutic failures, and confusion (caused by name, labeling, instructions, design or packaging)

- **View Submitted MedWatch Reports**

View some of the FDA MedWatch reports submitted to the NPA by people who have reported adverse reactions and product problems associated with their use of head lice and/or scabies treatment products. The reports are as originally submitted to the NPA's Reporting Registry with personal identifiers removed.

- **Comment Browser**

Comments, messages and personal stories that NPA receives every day via e-mail and this reporting registry.

- **Outbreaks of Lice or Scabies**

Let us know if you believe there is an outbreak in your school, child care center or community. Tell us where and we'll zip some educational info ASAP.

- **Skin Scraping/Collembola Research**

- **I am a medical/research professional**

- **I have been contacted for help by someone suffering from these or similar symptoms**

- **I may be suffering from this condition**

- **I am a member of the press/media**

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# MedWatch

Triage Unit Sequence #

## A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
125	10-23-62	female	140 lbs

## B. Adverse event or product problem

### Adverse Event & Product Problem

### Outcomes attributed to adverse event

☐ death      ☒ disability  
☐ life-threatening      ☐ congenital anomaly  
☐ hospitalization      ☒ required intervention  
 other: SIDE EFFECTS

Date of event 02-14-00      Date of report 03/15/00

### Describe event or problem

BROKE OUT ON HANDS ARMS SHOULDERS.& BELTLINE, JUST AFTER MY 7 YR OLD DAUGHTER CONTRACTED & I DID HER TREATMENT FOR HEAD LICE USING RID

### Relevant tests/laboratory data

### Other relevant history, including preexisting condition

PSORISIS, SINCE THE AGE OF 20. NOW APPEARS TO BE CLEARING UP FOLLOWING TRIAMCINOLONE .1% CREAM TREATMENT, HOWEVER, STILL DON'T SEEM 100% CURED

## C. Suspect medication(s)

Name: lindane

.1%, LOTION & SHAMPOO

### Dose, frequency, route use

2 OZS HEAD TO TOE, REPEATED SAME 10 DAYS FOLLOWING

### Therapy dates

02-14-00 to 3-14-00

### Diagnosis for use

SCABIES

### Event abated after use stopped or dose reduced

no

### Lot #

### Exp. date

### Event reappeared after reintroduction

yes

### NDC #

- -

### Concomitant medical products

TRIAMCINOLONE .1% CREAM

## D. Suspect medical device

### Brand name

### Type of device

### Manufacturer name and address

### Operator of device

☐ health professional  
☐ user facility  
☐ distributor

### model #

### catalog #

### serial #

### lot #

### other #

### Expiration date

### If implanted, give date

### If explanted, give date

### Device available for evaluation?

☒ yes    ☐ no    ☐ returned to manufacturer / /

### Concomitant medical products

## E. Reporter

### Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

### Health professional

☒ yes    ☐ no

### Occupation

### Also reported to

☐ manufacturer  
☐ user facility  
☐ distributor

If you do NOT want your identity

disclosed to the manufacturer, place an ☐

NPA 73132

# MedWatch

Triage Unit Sequence #

## A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
857	9-23-98	female	35 lbs

## B. Adverse event or product problem

### Adverse Event

### Outcomes attributed to adverse event

- ☐ death
 ☒ disability  
☒ life-threatening
 ☐ congenital anomaly  
☐ hospitalization
 ☐ required intervention

other:

Date of event 9/00/01 Date of report 05/14/02

### Describe event or problem

I have written to you before, months ago, about my daughter, she developed conjunctivitis and rash, well 9 months later and 10 doctors later she has been put on methotrexate and prednisone

### Relevant tests/laboratory data

### Other relevant history, including preexisting condition

no preexisting conditions

## C. Suspect medication(s)

Name: lindane

### Dose, frequency, route use

total of four times

### Therapy dates

9/00/01

to

10/00/01

### Diagnosis for use

doctor never saw us he called it in

### Event abated after use stopped or dose reduced

no

Lot #

Exp. date

### Event reappeared after reintroduction

doesn't apply

NDC #

-

-

### Concomitant medical products

## D. Suspect medical device

### Brand name

### Type of device

### Manufacturer name and address

### Operator of device

- ☐ health professional  
☐ user facility  
☐ distributor

model #

catalog #

serial #

lot #

other #

### Expiration date

### If implanted, give date

### If explanted, give date

### Device available for evaluation?

☒ yes
 ☐ no
 ☐ returned to manufacturer / /

### Concomitant medical products

## E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

### Health professional

☒ yes
 ☐ no

### Occupation

### Also reported to

- ☐ manufacturer  
☐ user facility  
☐ distributor

If you do NOT want your identity

disclosed to the manufacturer, place an ☐

NPA 73239

## **Chemical Remedies Threaten Children with Head Lice, According to the National Pediculosis Association**

PR Web Newswire  
January 4, 2007

*Chemical remedies threaten children with head lice.*

Needham, MA (PRWEB) January 4, 2007 -- The National Pediculosis Association® (www.HeadLice.org), the nation's leading non-profit health and education agency for safe and effective management of head lice, urges parents to get proactive and avoid using potentially toxic shampoos and lotions on children infested with head lice this winter.

Head lice are extremely common among children throughout the year. But the holiday season is a critical opportunity for parents to know what to look for and to screen their children in order to send them back to school lice and nit (lice eggs) free after vacation.

Head lice prevention can be accomplished easily through routine screening, early detection and thorough manual removal of all lice and nits. Head lice become more challenging the longer infestations go undetected.

The NPA advises parents to avoid combating this communicable disease with dangerous pesticides that are designed as neurotoxins and are potential carcinogens. "These treatments have more risk than benefit and are therefore totally inappropriate for the population of young children and families commonly affected by head lice," said Deborah Altschuler, President of The National Pediculosis Association. Families should especially avoid treatments that contain the chemical lindane, recently banned for agriculture by the EPA but unfortunately still prescribed for children with lice.

A Holistic Approach: The LiceMeister Comb® There are effective, non-toxic ways to control head lice, including use of the LiceMeister Comb®. "The NPA developed the LiceMeister comb as a practical and realistic alternative to what otherwise becomes excessive use of potentially harmful pesticides," stated Ms. Altschuler.

The NPA strongly urges a proactive prevention approach. Managing head lice by relying on treatments to which the lice are resistant promotes a crisis mentality. A lack of accurate information and preparedness results in too many treatment failures and too many days out of school. The LiceMeister comb offers the much-needed opportunity for early detection, safety and peace of mind. Proceeds from the comb help support the educational outreach programs of the NPA.

About The National Pediculosis Association,® Inc. The National Pediculosis Association (NPA) is the only non-profit health and education agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies pesticidal treatments. As part of its mission, the NPA works to encourage our nation's health and child care professionals to adopt standardized head lice management programs in an effort to keep the children in school lice and nit free.

## Child Care Provider's Guide To Controlling Head Lice

Pre-school children and their parents face many new challenges as they begin their first experience in a group setting. One of these challenges is the risk of children contracting head lice and the use of ineffective and potentially harmful chemical treatments.

Head lice are a common occurrence among young children who are most vulnerable to the dangers associated with the misuse and abuse of head lice treatments – the majority of which are pesticides. For this reason, child care providers should establish a proactive head lice management protocol before outbreaks occur.

Effective head lice control is based on a high standard of education, prevention and accountability for both parents and staff. Conflict arises when there is no standard in place.

By providing accurate information, you can minimize the need for crisis intervention, the use of pesticides on children and unnecessary disruption to the child care experience.

### Establish a Head Lice Control Standard

- Communicate your policy to your staff and teach them how to properly identify head lice and nits (lice eggs). The NPA's Critter Card presents a clear and realistic depiction of both lice and nits.

Staff members should understand the rationale behind your head lice standard.

Staff should be prepared to respond to child and parent questions.

Because dismissal can be awkward, be sure parents are aware of your policy on when a child will be dismissed and the conditions for their return.

- As part of your health registration guidelines, provide parents with your written policy and educational literature on prevention, detection and treatment of head lice.

Parents should understand the importance of screening often, detecting head lice and nits as early as possible and removing them safely and effectively. They should also understand the risks of using pesticidal lice products and be informed of non-chemical treatment alternatives.

- Announce regularly scheduled screening dates and send reminders the day before.

Notify parents in advance of any additional screening whenever possible.

- Reinforce your efforts by encouraging parents to make lice inspection part of the child's personal hygiene care at home. Screenings are most easily done as part of the child's normal routine – after bathing or showering when their hair would be combed anyway.

### Teach Screening Procedures

- Group inspections should be done with disposable screening sticks. Look for nits – tiny yellowish-white oval eggs firmly attached at an angle to the hair shaft. (The Critter Card is a useful tool.) Contrary to some claims, nits found more than a quarter inch from the scalp are not necessarily dead. Viable nits can be found anywhere on the hair. The diagnosis is made more often by seeing the attached nits than by finding crawling lice.
- Be sure not to confuse nits with hair debris such as DEC plugs (bright white irregularly-shaped clumps of dandruff stuck to the hair shaft), or hair casts (elongated segments of dandruff encircling the hair shaft).
- Although nits may be more prevalent at the nape of the neck, around the ears and at the crown of the head, check the entire scalp since nits can be found anywhere in the hair.
- Nits are tiny and can be difficult to remove. They are firmly attached to the hair shaft and cannot be brushed out or removed with a regular comb.
- Lice are about the size of a sesame seed, clear in color when first hatched and then become brown after they feed, and move quickly away from light.

- Two people checking through a child's hair at the same time can be helpful.
- If it is questionable if a child has nits, the LiceMeister® Comb can be used as a diagnostic tool.

### **Parent Notification**

- Promptly inform all parents when a case of head lice is detected.
- Alert parents to the risks of using pesticides.

Those especially at risk include:

- Women who are pregnant or nursing.
- Anyone on medication or who has a pre-existing medical condition such as allergies, asthma, epilepsy, cancer.
- Children under two years of age.
- Children who have been repeatedly exposed to chemical treatments.

Head lice treatment can be harmful both to the person applying the treatment and the person being treated. This is why the NPA encourages a non-chemical approach with manual removal whenever possible.

- Advise against treating anybody who is not infested and the use of repellents.
- Strongly discourage the use of products containing lindane. Lindane is a prescription lice product and a known neurotoxin and has been associated with adverse reactions ranging from dermatitis to seizures to death.
- Malathion is another pesticide prescription product that should be avoided. Unfortunately, it is often recommended when the child has already been exposed to other pesticide treatments that have failed.
- Additionally, both Lindane and Malathion are environmentally unfriendly and pollute the water supply when they are rinsed off.
- Over-the-counter head lice treatments are also pesticides and there are NO safe pesticides.
- Inform parents that none of the products are 100% effective.
- Based on scientific reports of lice resistance on a national level, the NPA advises parents to discontinue the use of lice products at the earliest sign of treatment failure. **MANUAL REMOVAL IS THE BEST OPTION WHENEVER POSSIBLE AND ESPECIALLY WHEN TREATMENT PRODUCTS HAVE FAILED.**
- Warn against the use of lice sprays. Recommend vacuuming as the safest and most effective alternative to spraying. Using lice sprays on bedding, furniture and carpets is unwarranted and poses both personal and environmental risks.
- It is unnecessary to bag objects that can't be washed such as stuffed animals. Vacuum them instead. Parents should save their time and energy for what will benefit them the most: thorough nit removal.
- Head lice cannot be gotten from—or given to—animals. They are “host-specific” and infest humans only.

### **Inspect Your Facility**

- Coats and hats should be hung separately and spaced so they do not touch. Lice do not hop, jump or fly.
  - Hats should be tucked into coat sleeves.
  - Coats should not be piled or stacked.
- Children should not share clothing or headgear.
- Review your policy on dress-up corners. Dress-up is a valuable play activity, but it can also be risky for head lice outbreaks. We recommend discontinuing shared dress-up clothing and replacing it

with disposable articles if possible.

- Sleeping mats or towels brought from home should be individually labeled and stored in separate cubbies or in a duffle-type bag. Ideally, such items should be laundered or vacuumed regularly.
- Carpeted areas should be vacuumed as often as possible.
- NEVER use pest extermination services for head lice: buildings don't get head lice - people do. Vacuum only.

### **Temporary Dismissal**

When a case of head lice is found:

- Infested children should be prepared for pick-up with a minimum of fuss. When the parent arrives, he/she should be given another copy of the Dear Parent Letter and your guidelines explaining that the child may return as soon as she or he is free of lice and nits. It is helpful to have effective lice combs on hand to ensure the child is treated safely and successfully and able to return as quickly as possible. The comb can also be used for parents to screen themselves.
- Notify all parents that lice have been found within the group and arrange for the entire group to be screened as soon as possible. Screenings can be conducted close to dismissal time in order to minimize disruption. Remind parents to check all their children carefully each day for the next few weeks and to continue checking as part of their routine hygiene.
- Be prepared to answer questions. Parents may feel overwhelmed and need to review the information from your health packet.
- Reassure parents that head lice do not necessarily reflect unsanitary households or neglected children. Learning that your child is being dismissed due to a head lice infestation can be distressing.
- Use a quality lice removal comb to examine children returning after an infestation to confirm successful resolution before the child re-enters the group. The comb will detect even what could be missed during visual inspection to ensure the child is lice and nit free.

### **Prevent New Outbreaks**

- Review procedures with staff and consider steps that many not have been regularly adhered to - separating sleeping mats, coats and hats.
- Remind children of the importance of not sharing headgear or personal articles.
- Remind parents of the importance of screening often, detecting head lice and nits as early as possible, removing them safely and effectively and continuing to screen as part of their routine hygiene.
- Encourage the children and help them feel comfortable about speaking up if they feel itchy.

### **Administrative Advantages of the No Nit Standard**


Having the No Nit standard in place makes head lice management more realistic and less subjective. As an administrative policy, it helps parents understand and assume their responsibility for head lice control. Families are encouraged and enabled to respond by carrying out the most effective prevention measures at all times and the safest most thorough control measures possible. The reward is an environment of mutual assurance that the child enters a group setting that supports a head lice control program.

### **Medical and Social Advantages of the No Nit Standard**

- Prevents continuing infestations caused by the surviving and hatching of nits.
- Maximizes the opportunity to eliminate repeated chemical treatments aimed at killing head lice that hatch from remaining viable nits.
- Eliminates confusion – Were these eggs here before or do they represent a new infestation?
- Contributes to improved standards of personal hygiene and self-esteem, protecting children from ridicule and rejection.
- Enhances uninterrupted group time for the majority of the children and prevents lost days at work



that can be costly for parents.

<b>GUIDE DEVELOPED BY:</b> National Pediculosis Association 50 Kearney Road Needham, MA 02494 (781) 449-NITS <a href="http://www.headlice.org">www.headlice.org</a>	 <a href="#">Click here for printable versions of this and other NPA publications</a>
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# I've Got You Under My Skin

## Important Diagnosis Information & Some Frequently Asked Questions About Scabies

### What is the most common symptom of scabies?

The most typical symptom of scabies is intense itching, particularly at night. Scabies and its associated itching occur most often between the folds of the skin, such as at the wrists and elbows, between the fingers, and in the general area of the navel and beltline. Infants and children sometimes get scabies on the head and scalp, or on the palms of the hands or soles of the feet.

### How do you get scabies?

Scabies is mainly transmitted from one person to another through close contact with an infested person, or by sharing his or her personal articles, such as clothing or bed linen. If you think you may have been exposed, or if you experience intense itching, consult your physician.

### Can you get scabies from pets?

The human scabies mite infests and reproduces only on humans. Scabies mites from other animals may cause limited local irritation but will not become an infestation.

### How is scabies diagnosed?

Dark ink applied to skin areas of suspected infestation help locate scabies' burrow sites. To confirm the presence of scabies, however, your physician places a drop of sterile mineral oil on the affected area. A scraping from this area is then examined under a microscope.

### Why is it important to see a physician?

Proper identification of scabies requires medical experience. Scabies is often accompanied by bacterial infections and is easily confused with other skin diseases. An accurate diagnosis is important because treatment for scabies requires the direct application of a prescription pesticide (scabicide) to the skin.

### Who is at risk?

Anyone of any age can get scabies, especially people living in crowded conditions.

### Can there be problems with treatment?

Young children, nursing mothers, pregnant women, elderly individuals, and people with pre-existing medical conditions may be more vulnerable to scabicide treatments. Most problems associated with using scabicides occur when people do not follow product instructions carefully. Side effects are often associated with improper use and unnecessary overtreatment. Some treatments, however, are more risky than others.

### Are there treatments I should avoid?

The National Pediculosis Association, Inc. (NPA) strongly discourages the use of scabicides that contain the chemical lindane. Lindane has been associated with a variety of serious medical problems, including seizures and cancer. Lindane products are available under various names, so it is important to check with your pharmacist about your prescription.

### Is there a safer alternative to lindane?

Yes. While all scabicides are pesticides and must be used with caution, products containing topical 5 percent permethrin are considered safer treatments than products containing lindane.

### Scabies is a highly communicable

Skin disease caused by tiny human itch mites. The presence of scabies mites is often indicated by tunnel-like lines of skin eruptions or bumps where female mites have burrowed under the skin to live and lay their eggs.

### Does the itching of scabies disappear after treatment?

Itching may continue for as long as two to three weeks after treatment. But this is normal, and

is not a reason to reapply the scabicide product.

**How do I treat the furniture and my home environment?**

Vacuuming is the safest and best way to prevent the spread of scabies from furniture and unwashables. Laundering bed linens, bath towels, and clothing in hot water is very important and should be a part of the treatment procedure. Avoid using potentially harmful pesticide sprays.

**Important Information for the Accurate Diagnosis of Scabies:**

Reports to the NPA continue to strongly suggest that prescribing a scabicide without critical evaluation can be counterproductive, if not harmful. It is unwise to treat for scabies (or any other disease) without a firm diagnosis because the person is not only exposed to unnecessary pesticides but is also delayed in getting an accurate diagnosis and proper therapy when scabies are not the culprits.

**Common Misdiagnosis**

Scabies can imitate many other skin conditions, such as insect bites, hives, eczema, folliculitis, contact or atopic dermatitis, impetigo, rosacea, psoriasis, lymphoma, and drug reactions.

**Diagnostic Tests**

According to the American Academy of Dermatology, the most common test involves applying a drop of sterile mineral oil to the suspected lesion. The site is then scraped with a scalpel and the scrapings are transferred to a slide. Under the microscope, the doctor should be able to find scabies mites, their eggs, or feces. Another option is an ink test, in which the doctor applies a blue or black felt-tipped pen to the suspected areas. Then the skin surface is cleaned. Mite burrows can be revealed if the ink sinks into them.

[Click here for a Diagnostic Quiz about Scabies from Para-Site Online](#)

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*National Pediculosis Association<sup>®</sup>, Inc.*

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## Lindane and Cancer

- **Evidence for Carcinogenicity Classification**
- **Evidence of Carcinogenicity Full Report Summary**

- Aplastic Anemia
- Breast Cancer
- Cancer Related Abstracts
- Endocrine Disrupting Chemical's
- Environmental Medicine, Part 1: The Human Burden of Environmental Toxins and Their Common Health Effects
- Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men

**Cancer Hazard** \* Lindane may be a **CARCINOGEN** in humans since it has been shown to cause liver, lung, endocrine glands and other types of cancer in animals. \* There is limited evidence that Lindane is associated with leukemia in humans. \* Many scientists believe there is no safe level of exposure to a carcinogen. Such substances may also have the potential for causing reproductive damage in humans. 1988

<http://chppm-www.apgea.army.mil>

### FARMING/NON-HODGKIN'S LYMPHOMA

A relationship between the use of high levels of pesticides 20 years ago and non-Hodgkin's lymphoma has been suggested in a National Cancer Institute study. DDT, carbofuran, and chloraben use were positively associated with non-Hodgkin's lymphoma while atrazine, cyanazine, glyphosate, lindane, and nicotine were associated with the development of small cell lymphocytic lymphoma. (American Journal of Epidemiology 122(3)535, 1985)

### IU Research Links Dieting Habits With Risk For Estrogen-Responsive Cancers

This study demonstrated that when beta-HCH, a compound in lindane, is released from fat it has a larger effect on the uterine tissue than did DDT-- a now-banned insecticide-- but DDT did have some estrogenic effect on uterine tissue.

Beta-HCH is less fat soluble and therefore more water soluble than DDT so it can get into the blood and travel to the breast, uterus and liver.

In a December 1996 study in Cancer Research, Dr. Bigsby and his colleagues showed that beta-HCH and DDT stimulated the growth of breast tumor tissue that was grafted into mice. Since the epithelial cells of the breast are surrounded by fat cells the effect of a diet-induced loss of fat may be of special concern with regard to the release of these xenoestrogens.

[http://www.medicine.indiana.edu/news\\_releases/archive\\_97/dietingandcancer2.htm](http://www.medicine.indiana.edu/news_releases/archive_97/dietingandcancer2.htm)

### Evidence for Carcinogenicity

Classification of carcinogenicity: 1) evidence in humans: inadequate; Overall summary evaluation of carcinogenic risk to humans is Group 2B: The agent is possibly carcinogenic to humans. /From table/ /Hexachlorocyclohexanes/

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work)., p. S7 64 (1987)]

\*\*PEER REVIEWED\*\*

CLASSIFICATION: B2; probable human carcinogen. BASIS FOR CLASSIFICATION: Assays in four strains of mice have yielded positive carcinogenicity results for t-HCH administered in diet. HUMAN CARCINOGENICITY DATA: Inadequate.

[U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) on technical Hexachlorocyclohexane (t-HCH) (608-73-1) Available from: <http://www.epa.gov/ngispgm3/iris> on the Substance File List as of March 15, 2000]\*\*PEER REVIEWED\*\*

TOXNET

## HEXACHLOROCYCLOHEXANE (TECHNICAL HCH AND LINDANE)

**Hexacyclohexanes are possibly carcinogenic to humans (Group 2B).**

**Group 2B: The agent (mixture) is possibly carcinogenic to humans.**

**The exposure circumstance entails exposures that are possibly carcinogenic to humans.**

This category is used for agents, mixtures and exposure circumstances for which there is *limited evidence* of carcinogenicity in humans and less than *sufficient evidence* of carcinogenicity in experimental animals. It may also be used when there is *inadequate evidence* of carcinogenicity in humans but there is *sufficient evidence* of carcinogenicity in experimental animals. In some instances, an agent, mixture or exposure circumstance for which there is *inadequate evidence* of carcinogenicity in humans but *limited evidence* of carcinogenicity in experimental animals together with supporting evidence from other relevant data may be placed in this group. Supplement 7: (1987) (p. 220)

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Carcinogenicity rating on chemicals

## IARC AND NTP CARCINOGEN LIST

Lindane Education And Research Network is a project of the National Pediculosis Association®

The NPA, a non-profit organization, provides these resources to you free of charge thanks to proceeds from our educational resources and sales of the LiceMeister Comb and LiceMeister Kit.

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## Lindane and Breast Cancer

- The organochlorine pesticide residues and antioxidant enzyme activities in human breast tumors: is there any association?
- Lindane and breast cancer - Why take risks?
- Xenoestrogens and Breast Cancer: Nowhere to Run
- Pesticides and Breast Cancer
- Organochlorines and Breast Cancer
- Risk Assessment of Breast Cancer in Women Due to Exposure to Organochlorines
- Organic Pollutants: Pesticides and Breast Cancer
- Breast Cancer and Pesticides in Hawaii
- Organochlorine Insecticides and Breast Cancer
- Linkage of Pesticides and Breast Cancer through Lactation Studies
- They make the chemicals, they run the treatment centers, and they're still looking for "the cure" — no wonder they won't tell you about breast cancer prevention.
- **Why? Mother Jones article**

"Another rather big issue in the UK is the very high levels of breast cancer, especially in certain agricultural regions," says Buffin. "We believe this may be associated with organochlorines, especially lindane, whose levels are particularly high in vegetable production." Lindane, an insecticide with a slow rate of biodegradation, has been detected in the blood and fat tissue of the general public in a number of countries, probably as a result of food contamination, according to a 1993 report by Physicians for Social Responsibility.

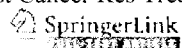
### Additional Resources:

THE WOMEN'S ENVIRONMENTAL NETWORK

Breast Cancer Fund

Cancer

Breast Cancer Res Treat. 2002 Mar;72(2):173-82.



Related Articles, Links

**The organochlorine pesticide residues and antioxidant enzyme activities in human breast tumors: is there any association?**

**Iscan M, Coban T, Cok I, Bulbul D, Eke BC, Burgaz S.**

Department of Toxicology, Faculty of Pharmacy, Ankara University, Turkey. iscan@pharmacy.ankara.edu.tr

The levels of some organochlorine pesticides (OCP)s (hexachlorobenzene, HCB, alpha-hexachlorocyclohexane, alpha-

HCH, beta-HCH, gamma-HCH, heptachlorepoxyde, HE, bis (4-chlorophenyl)-1,1-dichloroethene, p,p'DDE, bis (4-chlorophenyl)-1,1,1-trichloroethane, p,p' DDT and total DDT (E-DDT) and antioxidant enzyme activities namely Cu, Zn superoxide dismutase (SOD), catalase (CAT), selenium-dependent glutathione peroxidase (Se-GSH-Px), total glutathione peroxidase (T-GSH-Px), selenium independent glutathione peroxidase (GSH-Px II), glutathione reductase (GRd), level of reduced glutathione (GSH) and lipid peroxidation (LP), glutathione S-transferase (GST) activity toward several substrates including 1-chloro-2,4-dinitrobenzene (CDNB), 1,2-dichloro-4-nitrobenzene (DCNB), ethacrynic acid (EAA), 1,2-epoxy-3-(p-nitrophenoxy)-propane (ENPP) were measured in tumor and surrounding tumor free tissues of 24 female breast cancer patients and was evaluated whether there exist any association between the levels of OCPs and antioxidants. The mean levels of GSH, alpha-BHC, gamma-BHC and HE, and activities of SOD, Se-GSH-Px, T-GSH-Px, GSH-Px II, GRd, GST CDNB, and GST DCNB were significantly higher in tumors than in controls. In tumors, significant correlations were noted between: SOD and y-BHC; Se-GSH-Px and gamma-BHC; T-GSH-Px and gamma-BHC; GSH-Px II and alpha-BHC, gamma-BHC; GSH and alpha-BHC, gamma-BHC, HE; GRd and alpha-BHC; CDNB GST and alpha-BHC, gamma-BHC. These results show that free-radical mediated oxidative stress is, at least partly, associated with some of these OCP residues in human breast tumors.

PMID: 12038708 [PubMed - indexed for MEDLINE]

[http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\\_uids=12038708&dopt=Abstract](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12038708&dopt=Abstract)

## Lindane and breast cancer - Why take risks?

Between 1984 and 1994, seven international studies compared levels of organochlorines and other persistent chemicals in women with and without breast cancer. Four of the studies found higher levels in women with breast cancer, one did not and two were inconclusive. This prompted the idea first put forward by Devra Lee Davis and H. Leon Bradlow, two senior researchers at New York's Strang-Cornell Cancer Research Laboratory, that lindane is implicated in the growing incidence of breast cancer. Their theory is based on the concept that the OC pesticides and some other persistent chemicals such as polychlorinated biphenyls (PCBs) are capable of mimicking estrogen and thus of seriously disrupting the body's natural hormonal actions. The effects of these 'estrogenic' chemicals have also been associated with lower sperm counts in men and a range of reproductive abnormalities in wild fish and mammals.

Every year in Britain about 30,000 women and a few hundred men find a breast lump which proves to be malignant. Breast cancer is the most common type of cancer in women in the UK, England and Wales have the highest death rates from breast cancer anywhere in the world. While the disease clearly predates the introduction of organochlorine chemicals, rates have more than doubled this century and continue to rise between one and two percent each year.

A clear relationship between estrogen and breast cancer has been established in many studies<sup>6</sup>, thus giving rise to a theoretical mechanism by which estrogenic properties of lindane could increase breast cancer risk. Breast cancer, like other malignancies, occurs when a cell replicates abnormally and multiplies rapidly. It seems that estrogens from outside the body can combine with its natural estrogens to change the rate of multiplication of cells.

The World Health Organization has acknowledged that ninety percent of the lindane in our bodies comes from diet and it is known to accumulate in body fat where it increases with time.<sup>8</sup> Even the fetus is exposed to lindane through intake of the chemical by its mother and it has been detected in virtually all breast milk. The extent to which we, at the top of the food chain, may be affected by bio-accumulation of organochlorines from relatively tiny amounts in primary foods can be seen from a simple food chain analogy of water, plankton and fish. Levels in plankton can be thirty times higher than those in the water, while in the fish feeding on the plankton they can be over thirty thousand times higher.<sup>9</sup>

## Soil Association

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<http://www.soilassociation.org/SA/SAWeb.nsf>

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## Xenoestrogens and Breast Cancer: Nowhere to Run



By Luita D. Spangler

In 1990, Elihu Richter and Jerry Westin, two environmental specialists from Hebrew University's Hadassah School of Medicine, discovered a surprising glitch in otherwise universally depressing breast cancer statistics. They found that in the decade between 1976 and 1986, Israel was unique among 28 countries surveyed in that it actually registered a significant drop in breast cancer mortality. This was in spite of increasing risk factors in the Israeli population, such as per capita fat intake and increasing patterns of delayed pregnancy, and previous Israeli breast cancer rates that paralleled the international epidemic. As Westin noted, "All and all, we expected a rise in breast cancer mortality of approximately 20% overall, and what we found was that there was an 8% drop, and in the youngest age group, the drop was 34%, as opposed to an expected 20% rise. So if we put those two together, we are talking about a difference of about 50%, which is enormous."

Westin and Richter eventually connected this drop in breast cancer mortality to a 1978 Israeli ban on the use of three organochlorine pesticides (a ban, by the way, that was opposed by the Israeli cancer establishment). Prior to 1978, alpha-benzene hexachloride (BHC), gamma benzene hexachloride (lindane) and DDT were used heavily in Israeli cowsheds. As a result, the three pesticides heavily contaminated milk and milk products, at rates between 100 and 1,000 times greater than in the U.S., national public outcry resulted in legislation prohibiting these three pesticides.

Critics quickly challenged this suggested connection between breast cancer mortality and pesticide exposure, claiming that since most environmentally-induced cancers take at least twenty years to develop, the drop in mortality happened too quickly to associate with the prohibition of the three pesticides. In reply, Westin and Richter explained that **organochlorine pesticides are "complete" carcinogens, which both initiate and promote tumor growth, and whose presence (or absence) can change cancer statistics quite rapidly.**

Actually, **animal experiments conducted back in the 1960's proved that organochlorine pesticides caused breast cancer in rats.**

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## Pesticides and breast cancer

In Lincolnshire the breast cancer rate is 40% higher than the rest of Britain. It is being blamed on the widespread use of the pesticide lindane, mainly used on sugar beet crops. It is a known carcinogen and is completely banned in several countries. In Britain it is approved for use on fruit and vegetables, cereals, beans, sugar beet and oilseed rape. It is also used on trees, grass, in grain stores and insect repellents.

In the past, residues of lindane have been found both in cow's milk and human breast milk.

(*Health Guardian* 1.9.95 p. 3)

Edited from *Environment & Health News* Vol. 1. Issue 3. p.2

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## Organochlorines and Breast Cancer

### Summary

The relationship between organochlorine compounds and breast cancer is a controversial issue. We found original articles, reviews and opinion papers on this topic, including a summary of information presented at the "Workshop on Hormones, Hormone Metabolism, Environment, and Breast Cancer" held September 1995 in New Orleans (published in *Environmental Health Perspective* 105, Supplement 3, April 1997). We selected those papers that included comprehensive summaries of the evidence gathered so far, as well as some documents written by experts in this field. Obviously the evidence published so far is not conclusive. The two reviews by the Swedish group are probably the most comprehensive and updated. We found the most recent and relevant manuscript from authors that are well-recognized in this field including D. Davis, M. Wolff and S. Safe. We did not find regional or Canadian original studies on this issue, but rather a review by Houghton and Ritter from Guelph. Finally, the Cape Cod experience seems to be an interesting model for an ecologic approach to study breast cancer clusters. We will continue updating our list of selected articles as these issues unravel with new reports.

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## Risk Assessment of Breast Cancer in Women Due to Exposure to Organochlorines

## SUMMARY

Although the claim made by Krieger et al (1994) that exposure to organochlorines are not a risk factor for developing breast cancer could not be verified using risk analysis techniques, various trends among selected co-factors were consistent overall with previous studies. The body of research regarding exposure to DDT is beginning to suggest that there is a notable trend positively linking it to breast cancer incidence; a finding that runs contrary to the Krieger conclusion. In vitro studies have explored mechanisms that would allow DDT to promote the generation of new cells resulting in cancerous tumors. The link between PCB exposure and breast cancer is more complex. Future research needs to be focused on specific groups of PCB congeners whose behavior may be cancer promoting, protective, or neutral with respect to cancer. If studies, such as the Krieger study, only analyze for total PCBs then it is very probable that mixtures of all three types of PCBs are present and may cancel each other out. Because organochlorines are so persistent and pervasive in the environment, there is the potential for a large public health risk. The results of more PCB congener-specific studies are eagerly anticipated.

<http://www.crle.uoguelph.ca/users/kris/education/Cancer.htm>

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## Organic Pollutants

by Gina M. Soloman, MD, MPH

## PESTICIDES AND BREAST CANCER

Hoyer AP et al. Organochlorine exposure and risk of breast cancer. **Lancet** 1998; 352:1816-1820

In 1976, researchers obtained blood serum samples from 7712 women who participated in the Copenhagen City Heart Study. Over the intervening two decades, 240 women in the study who had serum samples later developed breast cancer. The stored serum of these cases and of 477 controls was analyzed for organochlorine pesticides with suspected estrogenic properties (**lindane**, chlordane, DDT, DDE, Beta-hexachlorocyclohexane, and dieldrin), and for PCBs. All women had measurable concentrations of DDT metabolites in their serum, 90% had detectable PCBs and Beta-HCH, and 78% had detectable dieldrin residues, even though all of these chemicals had been banned for decades in Denmark. The risk of breast cancer was more than twice as high in women with the highest serum concentrations of dieldrin compared with those with the lowest concentrations. A statistically significant dose-response relationship was found between dieldrin and breast cancer. Furthermore, the cancers in the women with higher dieldrin levels were more aggressive. Some association was also seen between Beta-HCH and breast cancer risk, but no association was found between PCBs, DDT metabolites, or any of the other pesticides and breast cancer.

<http://www.med.harvard.edu/chge/toxics11.html>

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"The future will depend"on our wisdom not to replace one poison with another."

*National Pediculosis Association® , Inc.*

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## Aplastic Anemia and Lindane

### 5.3.9.7 Carcinogenicity

Lindane has been classified as Group B2/C (probable/possible human carcinogen) (U.S. EPA, 1999c) and a cancer potency of 1.3 per mg/kg-d has been listed (HEAST, 1997). Lindane's related isomers, alpha and beta hexachlorocyclohexane, are classified as probable human carcinogens and have cancer potencies similar to that of lindane. In addition to tumors identified in experimental animals, human study data indicate that this chemical may cause aplastic anemia (U.S. EPA, 1993a).TOXICOLOGICAL PROFILE SUMMARIES FOR TARGET ANALYTES

## Aplastic Anemia Toxin Exposure

*By Lyle L. Sensenbrenner, M.D.*

In many cases, aplastic anemia has been clearly linked to exposure to certain toxins, although in many cases it is unlikely that a specific case can be identified. Overall there are certain groups of substances which have been clearly shown to be causative agents for aplastic anemia. These include:

1. Toxic chemicals;
2. Drugs and other medications;
3. Radiation; and
4. Viruses.

Although accidental exposure to radiation and viruses are very difficult for an individual to control, certain toxic chemicals and medications can frequently be avoided. All persons should take care not to be unduly exposed to potentially toxic chemicals or drugs, but this is especially important for patients who have recovered from aplastic anemia. The possibility that exposure to the same compound a second time may reinduce aplastic anemia is a very real one. Therefore, it is suggested that all patients avoid the following:

### Organic Solvents

**Organic Solvents - This is probably the most important group of chemical to avoid. This includes:**

- Benzene and all of its derivatives - Benzene is the starting compound in the manufacture of many substances. It exists in high amounts in gasoline (especially unleaded gas) moth balls and crystals, many organic solvents such as paint and varnish removers, varsol (oil removing solvent), dry cleaning solutions, some glues and household cleansers. The contents should list Benzene if it is contained in the material.
- Toluene - used alone as an organic solvent made from Benzene and frequently contaminated by Benzene.
- Carbontetrachloride - used in many dry cleaning solutions.
- Dichloro ethane, or dichloro ethylene, or trichloro ethane - frequently used in cleaning fluids, especially fluids made to clean metals, metal parts, automobile engines, computer parts or other metal surfaces which must be very clean.

### Insecticides

**There are a group of insecticides that have been implicated as potential causes of aplastic anemia. These include:**

- Chlordane - frequently used to prevent termites.
- Dichloro, diethyl, trichlorthane (DDT).
- Gammabenzene hexachloride (**Lindane**).
- Organophosphates - Parathion, diazinon, malathion, disyston, methylparathion, trichlorfon, dichlorvos, bromphen vinphos, nuvacron. CE

Most insecticides pose particular hazards to humans, and great care should be exercised with their use by all people at all times. In addition, there are many drugs (medications) that have been implicated as causes of aplastic anemia, or at least potentiating factors. These include:

1. Chloramphenicol (chloromycetin) - all forms, including eye drops.
2. Butazolidin (phenylbutazone).
3. Gold.
4. Colchicine.
5. Dilantin (phenytoin, hydantoin).
6. Several other anti epilepsy drugs.
7. Cancer chemotherapy drugs.
8. Thorazine and other phenothiazine.
9. Quinidine.

No drug should even be taken that is not absolutely necessary. Although "street" drugs (cocaine, heroine, PCP, etc.) have never been definitely shown to be a cause of aplastic anemia, there are strong statistical correlation between the use of these "drugs" and aplastic anemia. It is possible that these drugs predispose one to be susceptible to other drugs, or these "drugs" might be cut with materials containing toxic substances. They should definitely be avoided.

Certain other chemical substances are also "suspect" as agents causing harm to the bone marrow. These include:

1. Hair dyes (all types).
2. Herbicides (all types) - these are the substances that are applied to lawns or fields to kill various types of plants. A wide variety of these substances are now commercially available.
3. Insect killers that act at a distance such as flea collars for dogs and cats, and the "pest strips" available for room use.

One potential source of some of these compounds (insecticides, some of the organic solvents) has been ground water in areas where wells are used as the source of drinking water. Chemicals which have been found in such drinking water include thehalogenated hydrocarbons (di and tri chloro and fluoro ethane, or ethylene). The presence of these can be tested for if they are in question.

#### **Aplastic Anemia Foundation Of America**

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[http://www.ons.org/xp6/ONS/Library.xml/ONS\\_Publications.xml/CJON.xml/CJON2001.xml/September](http://www.ons.org/xp6/ONS/Library.xml/ONS_Publications.xml/CJON.xml/CJON2001.xml/September)

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# **EXHIBIT B**

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January 22, 2007

**VIA FEDERAL EXPRESS**

Deborah Z. Altschuler  
President  
The National Pediculosis Association, Inc.  
50 Kearney Road  
Needham, MA 02494

**Re: Lindane**

Dear Ms. Altschuler:

I write on behalf of our client Morton Grove Pharmaceuticals, Inc. ("Morton Grove") in relation to the National Pediculosis Association, Inc.'s ("NPA") publication of false advertising claims regarding two of Morton Grove's products, Lindane Lotion and Lindane Shampoo (collectively "Lindane"). Lindane, as you know, is a competitor with the LiceMeister® comb in the marketplace of products for the treatment of lice and scabies.

Morton Grove has learned that the NPA has published false advertising claims and defamatory comments to healthcare providers, institutions, associations, and patients through a variety of means, including www.headlice.org. Morton Grove is requesting that you immediately cease making such claims and statements. These claims and statements have caused and will continue to cause others to believe that Lindane is not a safe and effective product when used as directed, and does not alleviate affects of the diseases for which it is FDA-approved. The NPA's false advertising claims and false and defamatory statements have caused and will continue to cause Morton Grove to incur substantial damages.

As the sole United States manufacturer of Lindane, Morton Grove wholly stands behind the safety of its products and the health benefits they provide. The NPA has done a great disservice by widely disseminating such claims and statements to healthcare providers and patients about Lindane.

As a mechanism for profiting from additional sales of the LiceMeister® comb and in an effort to decrease Lindane sales, the NPA has published numerous statements that are false,

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misleading, and defamatory. These statements violate the Lanham Act, 15 U.S.C. § 1125(a), and constitute defamation.

As you know, Lindane is regulated and approved by the FDA as prescription medications for the "second-line" treatment for scabies, pubic lice and head lice, which are all highly contagious health conditions – some of which are sexually transmitted. These diseases affect adolescents, adults, and children; cause significant morbidity; and impact millions worldwide. These products have been used successfully in clinical practice for more than 50 years.

It is a matter of public record that both the FDA and the EPA, after repeated and exhaustive reviews by medical and scientific subject matter experts, have concluded that currently approved uses of Lindane medications do not pose a significant risk to public health or safety. Consistently, the FDA has maintained that the benefits of Lindane medications, when used appropriately, outweigh potential risks, a factor in the use of all medications. Petitions to ban their use have all been dismissed and determined to be without merit, including those submitted by the NPA. The FDA continues to support the use and manufacture of Lindane as a second-line therapy for patients who have no other options. Additionally, the Centers for Disease Control and Prevention (CDC), which helps to set practice standards for the medical community, include Lindane in its *Sexually Transmitted Disease Treatment Guidelines* for the treatment of scabies and pubic lice, consistent with the FDA-approved prescription labeling.

According to the FDA's Division of Drug Marketing and Advertising, advertisements, such as those contained on the NPA's website, may not use comparative test data or reference published reports, unless the representations made in the advertisement are supported by substantial evidence derived from adequate and well-controlled studies. We do not believe the NPA advertising claims discussed herein comport with this standard.

It is well established that the FDA has the jurisdictional authority over the decision of whether a particular pharmaceutical product should or should not be on the market. Under applicable law, the "FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective" based upon "a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance." (Department of Health and Human Services, Food and Drug Administration, [Docket No. 2000N-1269] (formerly Docket No. 00N-1269) January 24, 2006.)

We are hereby demanding a retraction of all such statements by the NPA. We are prepared to allow a reasonable time for the NPA to prepare and distribute a retraction. The requested retraction must be circulated in the same scope and manner (specifically, your website,

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e-mail, correspondence, fact sheets, or other written and oral communications) as other publications that contained your false statements. We are prepared to allow up to two weeks, through February 5, 2007, for the NPA to prepare and issue this retraction. We would request a written confirmation of the persons to whom you will direct this retraction and a copy of the retraction.

In the event that the NPA ignores this request and/or refuse to issue a retraction, please understand that Morton Grove is prepared to take legal appropriate action.

This letter will also serve to document the false advertising claims and statements that Morton Grove currently believes the NPA has made which are to be the subject of the requested retraction.

The false statements the NPA made include, but are not limited to, the following:

**False Statement:** "symptoms" from "exposure" to Lindane include: "acute renal failure with azotemia, ADD/ADHD[,] anxiety, autism, atonia, agranulocytosis, aplastic anemia, anorexia, apprehensive mental state, behavior-mood disturbances, bullae, cancer, cardiac arrhythmias, clumsiness, coma, confusion, conjunctivitis, convulsions, cough, cyanosis, death, dermatitis, diaphoresis, diarrhea, disorientation, dizziness, dyspnea, emotional liability, excitement, excessive hair growth, fast heartbeat, fatigue, fever, giddiness, grinding teeth, headaches, heart palpitations, hematuria, hyperirritability, hypersensitivity, incoordination, kidney damage, liver damage, liver enlargement, loss of appetite, mania, mental retardation, muscle cramps, muscle spasms, muscle tremors, nausea, nervousness, oliguria, pallor, paraesthesia, paresis, paresthesia, porphyria, proteinuria, pulmonary edema, restlessness, respiratory failure, seizures, shaking, sweating, tachycardia, tearing, thirst, trouble breathing, trouble swallowing, urticaria, vertigo, vomiting, weakness, wheezing, elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes."

**Facts:** This claim is false, misleading and inaccurate, and it falsely portrays the safety profile of Lindane. The vast majority of these alleged side-effects are not listed in the FDA-approved prescription label for Lindane, and they also do not reflect the events reported to the FDA through their Adverse Event Reporting System Database (1951 – 2003) or to Morton Grove since they acquired the medications in 1995. You have not made any effort to support this highly misleading and injuring claim.

**False Statement:** "Illinois Bans Lindane"; "Illinois banned Lindane"

**Facts:** The State of Illinois has never banned Lindane.

**False Statement:** Lindane is "sold or prescribed without adequate warnings or guidance on use. It is applied to the scalp and overuse is encouraged."

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**Facts:** Quite the opposite, Morton Grove and the FDA have taken significant steps to discourage overuse, including (1) adding a boxed warning, (2) issuing a public health advisory, (3) repackaging the product in small, single-use bottles, and (4) distributing legally required patient guides with every Lindane prescription.

**False Statement:** "When these [first-line] treatments fail, the guidelines unfortunately recommend the prescription pesticides malathion and Lindane. There are health risks inherent with the use of pesticides on children and these risks increase dramatically when you follow one chemical treatment with another."

**Facts:** There is no credible scientific evidence to support the statement that "risks increase dramatically when you follow one chemical treatment with another." In fact, the Centers for Disease Control and Prevention and the American Academy of Pediatrics recommend the practice of using over-the-counter products first and then using Lindane if those are not effective. This recommendation, which is also supported by the FDA, is implicit to the use of "second-line" medications like Lindane Lotion and Lindane Shampoo,

**False Statement:** "[T]he main source of lindane in sewers is from the treatment of head lice and scabies and that a single treatment of lindane pollutes 6 million gallons of drinking water."

**Facts:** This statement is false. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had Lindane levels that were above conservative levels considered safe. (United States EPA Review of Drinking Water Standards, 2003.) The United State Geologic Survey also conducted large-scale contaminant testing of 139 streams near large cities and farms across 30 states and found that 93.9% of the samples tested negative for Lindane. Of the 5.9% of samples that tested positive, all were well below levels considered unsafe. (Kolpin DW, et al. 2002.)

The EPA sets Maximum Containment Levels (MCL) for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for Lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of Lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping Lindane levels below the more conservative 1991 MCL of 0.2 ppb. (United States EPA Review of Drinking Water Standards, 2003.)

To strike home how preposterous the above "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., D.A.B.T., A.T.S., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" analysis that if 100% of prescribed Lindane shampoo and lotion sold in the Albany, New York area (based upon the proportional number of New York 2004 prescriptions) was instead poured directly into Albany's drinking water supply, Lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the level considered safe in 2003.



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The EPA has similarly concluded in its most recent scientific evaluations of Lindane, as previously stated, that, "[T]he Agency does not have risk concerns for concentrations of Lindane in surface water used as a source of drinking water from consumer use for both lice and scabies." (United States EPA Lindane RED, 2002.)

**False Statement:** "When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school safe, lice and nit free."

**Facts:** While appropriate for patients who are not candidates for pediculicidal therapy, the scientific evidence for the effectiveness of combing in controlling lice infestations is generally considered to be lacking. In a rigorous head-to-head clinical study published in *Lancet*, manual removal of head lice with a commercial combing kit was found to be less than half as effective as treatment with a prescription pediculicide. (Roberts RJ, et al. 2000.) In fact the 2006 Cochrane Systematic Review of head lice treatments (an independent, authoritative analysis of evidence-based research) states: "The results of the trial by Roberts et al (2000) indicate that physical control methods, such as combing/'BugBusting' are ineffective as a means of curing head lice infections. This type of method of intervention is very labour intensive and requires a certain level of skill to be effective, which makes the treatment inappropriate as a primary treatment against head louse infestation." (Dodd CS. 2006) Indeed, Both the CDC and the American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over manual removal with special combs for the treatment of head lice. (Frankowski BL, et al. 2003; United States CDC Head Lice Fact Sheet, 2005.)

**False Statements:** The NPA attempts to convince consumers that using Lindane medications cause cancer. For example, they note: "[T]he U.S. EPA classifies lindane as a possible carcinogen" and that "Lindane should be handled as a **CARCINOGEN WITH EXTREME CAUTION.**" Similarly, the NPA states: "Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos."

**Facts:** These statements are false. First, there have been no established links between the use of Lindane and the development of cancer, despite more than 50 years of clinical use on adults and children. This is supported, in part, by the results of an epidemiologic study published in 1997 involving more than 140,000 patients and up to 21 years of patient follow up, which concluded, "There is still no persuasive evidence from studies of humans that lindane, as ordinarily used clinically, is carcinogenic in humans." (Friedman GD. 1997)

Second, while it is true that Lindane was previously classified as a "possible/probable" carcinogen, in 2001 the EPA downgraded the carcinogenic potential of Lindane to the same low-level rating as other first-line scabies and lice medications, such as permethrin (Nix) and malathion (Ovide), concluding that, "[q]uantification of human cancer risk is not required." (United States EPA 2001) In 2004, the World Health Organization (WHO)



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January 22, 2007

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further concluded that, "In the absence of genotoxicity [ability to damage DNA] and on the basis of the weight of the evidence from the studies of carcinogenicity, JMPR [Joint Committee on Pesticide Residues] has concluded that lindane is not likely to pose a carcinogenic risk to humans." (WHO Drinking-Water Quality, 2004; United States EPA (Malathion) 2000; PAN Pesticides Database (Permethrin)).

Similarly, the NPA's statement regarding childhood brain cancer is also scientifically unsupported as determined by the FDA. In fact, the "case-controlled" research cited by the NPA (Davis et al. 1993) prompted a special review by the FDA's Dermatologic Advisory Committee the same year it was published, concluding that, "[T]here were several flaws in the data presented in the article and that there was an unlikely association based on the data. The committee voted that lindane was safe when properly used, and that it should remain on the market" (United States FDA, Lindane Assessment Memo, 2003) No change in the lindane prescription labeling was considered necessary.

\* \* \* \* \*

The false advertising claims and statements identified in this letter have and will continue to cause harm to Morton Grove. Morton Grove demands that the NPA issue a prompt and full retraction. Again, we also request that you promptly confirm in writing that you intend to comply with this demand for retraction and that you will provide a copy of the retraction and a list of the names and addresses of any individuals or entities that receive the retraction. As noted, we are prepared to provide you up to February 5, 2007 to prepare and issue this retraction. In the event the NPA ignores this request and refuse to issue the retraction, Morton Grove will pursue all available legal remedies.

Sincerely,

  
W. Gordon Dobie

# **EXHIBIT 2**

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

MORTON GROVE	)	
PHARMACEUTICALS, INC.	)	
	)	
Plaintiff,	)	No: 08-CV- <a href="#"><u>1384</u></a>
	)	
v.	)	<a href="#"><u>Judge Bucklo</u></a>
	)	<a href="#"><u>Magistrate Judge Mason</u></a>
THE NATIONAL PEDICULOSIS	)	
ASSOCIATION, INC.,	)	
	)	
Defendant.	)	<b>JURY TRIAL DEMANDED</b>
	)	
	)	
	)	

**AMENDED COMPLAINT**

Plaintiff, Morton Grove Pharmaceuticals, Inc. (“Morton Grove”), by and through its attorneys, Winston & Strawn LLP, for its [Amended](#) Complaint against the National Pediculosis Association, Inc. (the “NPA”), states:

**Nature of Action**

1. This is an action brought to redress false, misleading, and deceptive statements and comparative advertisements regarding two FDA-approved drugs—Lindane Lotion and Lindane Shampoo—prescribed for the treatment of lice and scabies.

2. Plaintiff Morton Grove is a pharmaceutical company. Defendant NPA is the distributor of the LiceMeister® Comb, which competes with Lindane medications. While the NPA refers to itself as an “agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies

pesticidal treatments” and masquerades as a health organization, upon information and belief, the NPA does not employ a single physician or licensed health professional. It is a competitor of Morton Grove. In fact, in 2003, 97% of the NPA’s revenues were derived through the sale of LiceMeister® combs.

3. Morton Grove brings this action against the NPA for violation of the Lanham Act, trade disparagement, and violation of the Illinois Deceptive Trade Practices Act.

4. Morton Grove is the only United States manufacturer and distributor of Lindane medications. As such, the NPA’s statements regarding “lindane” necessarily refer to Morton Grove and its products.

5. Lindane medications have been approved by the Food and Drug Administration (“FDA”) as safe and effective prescription therapy for the treatment of lice and scabies. These infections, some of which are sexually transmitted, are increasingly resistant to certain treatments and remain important public health problems that affect tens of millions of Americans each year.

6. In the 50+ years that Lindane medications have been on the market, subject matter experts working with the FDA and the Environmental Protection Agency (“EPA”) have reviewed the weight of medical and scientific evidence on Lindane medications and repeatedly determined that these medications are safe and effective when used as directed. The FDA has consistently maintained its position that the benefits of Lindane medications outweigh the risks—a factor for all medications—and should remain an option for physicians. Petitions, including

one filed by the NPA, to ban Lindane medications have repeatedly been denied and determined to be without merit.

7. Similarly, the EPA has concluded that pharmaceutical Lindane poses no significant risk to humans or the environment when used as currently labeled.

8. The public health benefits of Lindane medications are further supported by the recommendations of the Centers for Disease Control and Prevention (“CDC”). The CDC sets practice standards for the medical community and includes Lindane medications in its Sexually Transmitted Disease Treatment Guidelines for the management of scabies and pubic lice, consistent with the FDA-approved prescription labeling for Lindane Lotion and Lindane Shampoo.

9. Moreover, in 2003, important advancements to the packaging and prescription of Lindane medications manufactured and sold in the United States served to mitigate the potential risks associated with product misuse and further enhanced their public safety.

10. Lindane Lotion and Lindane Shampoo are named after their active ingredient, lindane. Historically, lindane was used primarily in an agricultural context—more than 99% of lindane was used agriculturally, while less than 1% was used pharmaceutically (e.g., 99.7% agricultural v. 0.3% pharmaceutical in 2006). The dangers associated with chronic occupational exposure to agricultural lindane have been widely and unfavorably reported. These dangers differ vastly from those associated with the short-term topical application of small amounts of Lindane medications to the hair and skin—just 4 minutes in the case of head lice.

11. Despite this well-documented scientific, medical, and regulatory history, the NPA has launched an attack campaign on Lindane medications. The NPA swaps agricultural and pharmaceutical research, selectively quoting and/or misstating findings from studies relating to the agricultural use of lindane, and widely disseminates false, misleading, and deceptive statements about the safety profile and effectiveness of Lindane medications. These statements have created confusion in the marketplace and affected purchasing and prescribing behavior, negatively impacting both the sale of Lindane medications and Morton Grove's business.

#### **Parties**

12. Morton Grove, a Delaware corporation, is a pharmaceutical company with its principal place of business in Morton Grove, Illinois.

13. Upon information and belief, the NPA, a Massachusetts corporation, is based in Needham, Massachusetts. The NPA widely distributes information and products nationally, including in Illinois, through its interactive websites [www.headlice.org](http://www.headlice.org) and [www.lindane.org](http://www.lindane.org), which attract as many as 100,000 hits per day from thousands of unique visitors in the United States and around the world. The NPA sells its products nationally and has profited from the sales of the LiceMeister® comb in Illinois.

### **Jurisdiction & Venue**

14. This Court has jurisdiction over the subject matter of this action based upon the federal question presented by the Lanham Act, 15 U.S.C. § 1125(a) et seq., pursuant to 28 U.S.C. § 1331, and supplemental jurisdiction of the state law claims pursuant to 28 U.S.C. § 1367.

15. The Court has jurisdiction over the NPA based on their substantial contacts with the State of Illinois, including their commission of tortious acts which caused injury in the State of Illinois.

16. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

### **Factual Allegations**

#### **I. Background on Lindane Medications**

17. Morton Grove is the sole United States distributor of Lindane Shampoo and Lindane Lotion.

18. Lindane Lotion and Lindane Shampoo are prescription medications for the treatment of scabies, pubic lice, and head lice. These conditions are highly contagious public health conditions, some of which are sexually transmitted. These diseases affect adolescents, adults, and children, causing significant morbidity that impacts tens of millions of Americans.

19. Lindane medications have been used successfully in clinical practice for more than 50 years.

20. The FDA and the EPA, after numerous exhaustive reviews of the weight of evidence on Lindane medications, have concluded that currently approved

medical uses of Lindane medications do not pose a significant risk to public health or safety. In fact, Lindane medications have been reviewed by the FDA more than a dozen times beginning in 1951, and with each review the “FDA has determined that lindane products have benefits that outweigh risks when used as directed.” Woodcock, J. (Director, FDA Center for Drug Evaluation and Research), “Re: Docket No. 95P-0018/cP,” Correspondence to Jill A. Cashen, Cancer Prevention Coalition, May 13, 1997; U.S. Food and Drug Administration, Lindane Assessment Memorandum (2003). In 2001, the EPA even downgraded the cancer classification of lindane to a level that is in fact lower than the most commonly used first-line, over-the-counter medication permethrin (active ingredient in Nix®), and concluded that no additional cancer risk assessments of lindane in humans were necessary.

21. The CDC and the American Academy of Pediatrics (“AAP”) both recommend pediculicidal treatments—which Lindane medications are considered—over wet combing for the management of head lice, as combing leads to dramatically lower rates of clinical cure than chemical treatments.

## **II. The NPA Attempts to Increase Sales of the LiceMeister® by Distributing False, Misleading, and Deceptive Advertisements Regarding Lindane Medications**

22. Blindly ignoring well-established science and the positions of the FDA, EPA, CDC, and AAP on Lindane medications, the NPA has launched an attack campaign against Lindane medications in the hopes that it can increase sales of the LiceMeister® comb. This for-profit campaign blatantly ignores all standards for comparative marketing, including those promulgated by the FDA’s Division of Drug



Marketing and Advertising, which prohibit all such advertisements unless the representations made in those advertisements are supported by substantial evidence derived from adequate and well-controlled studies. See 21 U.S.C. § 355(d). In addition, the NPA violates norms and rules of advertising established by the FTC. See 15 U.S.C. § 45; 15 U.S.C. § 52; 16 C.F.R. § 14.15. Examples of the NPA's false advertising claims and other false statements referenced infra are attached as Exhibit A. Recent NPA employees admitted in depositions that they have no scientific background or training, did nothing to verify that the posted material was correct, and did not vet the information with any scientists or licensed medical professionals.

23. On this commercial website, the NPA has posted several hundred MedWatch forms which it has completed. MedWatch forms are typically used by consumers and their healthcare providers to report to the FDA adverse experiences that consumers have had with various drugs. Here, the NPA solicits data from visitors to its website, uses that data to complete MedWatch forms, signs its name to these forms as the reporter, and submits the forms the FDA. Next to its name, the NPA indicates that it is a "Health professional."

24. In fact, the NPA is not a "Health professional"—none of the members of its Board of Directors and none of its employees are licensed healthcare professionals, such as physicians, pharmacists, or nurses. Nor does the NPA have any proximity to or involvement in the actual treatment of the patient, as is typical when a medical professional submits a MedWatch form. The repeated

representations that the NPA is a “Health professional” are false and misleading, contribute to the illusion of medical credentials that the NPA projects on its website, and are part of the context in which the NPA’s false statements were made.

25. The overall context and message of the NPA’s website, identified in Paragraph 13, and statements creates with the viewer a false impression that misrepresents: (1) Lindane medications’ effectiveness; (2) Lindane medications’ harm to the environment; (3) that if you use Lindane medications, you significantly increase the risks of developing cancer and other serious adverse health effects; and (4) the NPA’s statements are objective, represent the scientific norm, and come from scientifically- and medically-credentialed individuals.

26. ~~23.~~ In an effort to maximize profits, the NPA has falsely claimed that the “symptoms” from “exposure” to Lindane medications include:

acute renal failure with azotemia, ADD/ADHD[,] anxiety, autism, atonia, agranulocytosis, aplastic anemia, anorexia, apprehensive mental state, behavior-mood disturbances, bullae, cancer, cardiac arrhythmias, clumsiness, coma, confusion, conjunctivitis, convulsions, cough, cyanosis, death, dermatitis, diaphoresis, diarrhea, disorientation, dizziness, dyspnea, emotional lability, excitement, excessive hair growth, fast heartbeat, fatigue, fever, giddiness, grinding teeth, headaches, heart palpitations, hematuria, hyperirritability, hypersensitivity, incoordination, kidney damage, liver damage, liver enlargement, loss of appetite, mania, mental retardation, muscle cramps, muscle spasms, muscle tremors, nausea, nervousness, oliguria, pallor, paraesthesia, paresis, paresthesia, porphyria, proteinuria, pulmonary edema, restlessness, respiratory failure, seizures, shaking, sweating, tachycardia, tearing, thirst, trouble breathing, trouble swallowing, urticaria, vertigo, vomiting, weakness, wheezing, elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes.

27. ~~24.~~ In fact, the overwhelming majority of these so-called symptoms or side effects nowhere appear on the FDA-approved prescription label for Lindane Lotion or Lindane Shampoo and are not reflected in the events reported to the FDA through its Adverse Event Reporting System Database or to the manufacturer.

28. ~~25.~~ In addition to mischaracterizing the safety profile of Lindane medications, the NPA has also misclassified its regulatory status, claiming “Illinois Bans Lindane” and “Illinois Banned Lindane.” The truth is that Illinois has not banned lindane. Following the filing of Morton Grove's complaint, the NPA removed these false statements from its website.

29. ~~26.~~ The NPA's website also falsely claims that “one dose of a lindane treatment for head lice can pollute 6 million gallons of water to levels exceeding drinking water standards.”

30. ~~27.~~ Like many of the NPA's other statements, this statement is scientifically unsubstantiated and runs counter to the conclusions of subject matter experts working with the EPA. In fact, the EPA has determined in its most recent assessment of lindane that the amount of pharmaceutical lindane reaching drinking water supplies is insignificant and not of concern.

31. ~~28.~~ Even unrealistic, worst-case estimates show that if Lindane medications were dumped directly into the drinking water supply (and not washed down the drain and out of the water supply and then diluted many thousand fold when reintroduced into large bodies of water as would normally occur), lindane

levels would still be 67 to 333 times lower than the level considered safe by the EPA.

32. ~~29.~~ These findings are further reinforced by real-world data from large-scale water contamination studies which show that lindane is not a water contaminant of concern, and that levels—when rarely detected—are well below standards established by the EPA for safe drinking. For example, a 2003 survey of water contamination, which involved the testing of 16,000 water systems serving 100 million people across the US, conducted by the EPA found that 0% exceeded conservative levels considered safe. Federal Register 68(138) (July 18, 2003). Similar findings were noted by the United States Geological Survey in 1999 and 2000 where water samples near large cities and farms were tested across 30 states and all found to be well within established EPA standards. Kolpin DW, Furlong ET, Meyer MT, et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. streams, 1999–2000: A National Reconnaissance. *Environ Science Technology*, 2002; 36(6):1202–1211.

33. ~~30.~~ In addition, an almost identical statement was retracted by the NPA's former co-defendant, the Ecology Center, Inc., who noted that the EPA “does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use [of lindane] for both lice and scabies.” See <http://www.ecocenter.org/safekids/clarifications.pdf>.

34. ~~31.~~ The NPA has received information from Morton Grove and others that its claim that "one dose of lindane" contaminates 6 million gallons of drinking water is false and misleading.

35. ~~32.~~ Despite knowledge of this statement's falsity, it remains on the NPA's website today.

36. ~~33.~~ The NPA does not stop there in its efforts to "scare" consumers into using its product, the LiceMeister® comb; it also attempts to convince consumers that using Lindane medications cause cancer. For example, it argues that: "[T]he U.S. EPA classif[ies] lindane as a possible human carcinogen" and "Lindane should be handled as a **CARCINOGEN WITH EXTREME CAUTION.**"

37. ~~34.~~ This statement is false and is not supported by the weight of scientific evidence or determinations published by the EPA, World Health Organization, and other subject matter experts.

38. ~~35.~~ In fact, the NPA's former co-defendant, the Ecology Center, Inc. issued a retraction noting that current information on the EPA's website notes that the EPA updated the cancer classification of lindane in 2003 to "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans." See <http://www.ecocenter.org/safekids/clarifications.pdf>

39. ~~36.~~ Lindane's carcinogenic risk is now considered by the EPA to be on par with malathion (active ingredient in FDA-approved lice treatment Ovide) and even lower than the most commonly used first-line, over-the-counter treatment permethrin (active ingredient in Nix).

40. ~~37.~~ The NPA also has stated: “Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos.” There, however, have been no established links between the use of Lindane medications and the development of cancer, despite more than 50 years of clinical use on adults and children. The “case-controlled” research cited by the NPA prompted a special review by the FDA that subsequently concluded: “[I]t was unlikely that the data in the Davie et al. study established any link between the increased incidence of childhood brain cancer and the use of Lindane 1% . . . shampoo, and that there was no need to make any changes in the current labeling for [Lindane medications].”

41. ~~38.~~ The NPA has also claimed that: “Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death.”

42. ~~39.~~ With respect to the NPA’s allegation that the use of lindane medications is associated with leukemia, the NPA’s former co-defendant, the Ecology Center, retracted a similar statement, which notes that in this particular study, only “[s]ix of the 568 children participating in this study were treated with lindane shampoo.” As the Ecology Center conceded, the study’s only conclusion with respect to lindane medications was that the issue “requires further study” in light of the “reported 95% confidence interval for lindane was CI 0.5 to 8.7,” which

is not statistically significant.

See

<http://www.ecocenter.org/safekids/clarifications.pdf>.

43. ~~40.~~ In a further effort to divert customers from Lindane medications to the LiceMeister® comb, the NPA's website also contains the following false and deceptive statements and misleading "warnings":

- "Be Sure You Provide a Non-Chemical Choice For Your Children . . . Because it's not worth taking unnecessary risks when the bottom line will always be the manual removal of lice and nits."
- "Never resort to **dangerous remedies** such as lindane, kerosene, or pet shampoos." (emphasis supplied).
- "When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school safe, lice and nit free."
- "Do not recommend products containing lindane. The Food and Drug Administration (FDA) regards it as potentially more toxic than all other pediculicidal choices and no more effective."

44. ~~41.~~ Finally, in an effort to sell additional LiceMeister® combs, the NPA has attempted to scare potential and actual consumers of Lindane medications with a "parade of horrors" regarding the effects of occupational exposure to agricultural lindane. These statements include:

- "Lindane is quite toxic to humans. The acute (short-term) effects of lindane through inhalation exposure in humans consist of irritation of the nose and throat and effects on the blood and skin. Chronic (long-term) exposure to lindane by inhalation in humans has been associated with effects on the liver, blood, and nervous, cardiovascular, and immune systems."
- "Chronic effects include damage to the nervous system and liver disease. Worker exposures have resulted in blood disorders, headaches,

convulsions, and disruption of the reproductive hormones of the endocrine system.”

45. ~~42.~~ These statements are wildly misleading in context, as the FDA has concluded that the “risk of occupational/environmental exposure should be assessed separately and independently of the risk related to the therapeutic use of a medication to treat a medical condition where there is a direct benefit to the patient.” The EPA shares this position.

46. ~~43.~~ Indeed, the NPA’s former co-defendant, the Ecology Center, Inc. published a retraction that clarifies this, noting that “the majority of such [adverse reactions] have resulted from oral ingestion (which is not how lindane medications are directed to be applied).” See

<http://www.ecocenter.org/safekids/clarifications.pdf>.

47. ~~44.~~ Upon information and belief, the NPA has never performed, prior to publication of the aforementioned statements, any tests comparing the qualities and characteristics of the LiceMeister® comb and Lindane medications, or evaluating the qualities and characteristics of Lindane medications.

### **III. As a Result of the NPA’s Actions, Morton Grove Has Been Harmed**

48. ~~45.~~ As a result of the NPA’s foregoing statements, Morton Grove has suffered incalculable financial and reputational injury to its business, including lost sales of Lindane medications and diminished goodwill.

49. ~~46.~~ The NPA’s statements, for example, contributed to a decrease in Morton Grove’s sales of 23%, or \$9.3 million, from January 2006 to November 2006.



50. ~~47.~~ The NPA's statements are viewed up to 100,000 times per day on the NPA's website, and they have deceived consumers and physicians into falsely questioning the safety and effectiveness of Lindane medications, thereby materially affecting purchasing and prescribing behavior for Lindane medications.

51. ~~48.~~ Moreover, the NPA has crafted its website in a manner to most effectively disseminate the aforementioned false and misleading statements, directing users to "see what we want them to see and avoid what we don't."

52. ~~49.~~ The NPA itself has acknowledged that its statements have affected Morton Grove's sales, noting that "sales figures for lindane products (Kwell, etc.) have fallen dramatically . . . . By targeting parents for re-education along with health professionals, we have ensured that the message travels up as well as down, and takes root in the process."

#### **IV. The NPA's Statements Were Made Intentionally & Maliciously**

53. ~~50.~~ In light of the statements' significant impact on Morton Grove's business, Morton Grove sent the NPA a letter (attached as Exhibit B) indicating that the NPA was publishing false, misleading, and deceptive statements about Lindane medications which were harming Morton Grove. This letter detailed each such false statement (either identical or similar to those included in this complaint), provided factual support for why each statement was false, and gave the NPA time to retract such statements. In addition, Morton Grove previously filed suit against the NPA on February 6, 2007 in the Northern District of Illinois (No. 06-CV-3815), from which this action was severed.

54. ~~51.~~ Despite this opportunity, the NPA failed to retract its false, misleading, and deceptive statements and continues to allow the publication and dissemination of these statements, even after receiving information that certain of these statements were false.

55. ~~52.~~ The NPA's continued publication of these statements, despite knowing their falsity, demonstrates the NPA's malicious intent to inflict harm on Morton Grove.

**COUNT I**  
**LANHAM ACT (15 U.S.C. § 1125(a))**

56. ~~53.~~ Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through ~~52~~55 of this Complaint.

57. ~~54.~~ The NPA sells a lice treatment product called the LiceMeister®, which it promotes as an alternative to Lindane medications.

58. ~~55.~~ The NPA's statements, through its website and sales of its product, have been made in interstate commerce and were, are, and continue to be made intentionally and willfully.

59. ~~56.~~ The NPA's advertising claims set forth above are false and misleading descriptions and representations of fact about Lindane medications. In addition, these statements are misleading in context and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

60. ~~57.~~ The NPA's false and misleading advertising claims have deceived and have the tendency to deceive a substantial portion of the target audience for lice and scabies treatments.

61. ~~58.~~ The NPA's false and misleading advertising claims are material to consumers' purchasing decisions.

62. ~~59.~~ The NPA has caused its false and misleading advertising claims to enter into interstate commerce.

63. ~~60.~~ The NPA's false and misleading advertising claims have caused certain consumers to not purchase Lindane medications. These claims have caused and are continuing to cause damage to Morton Grove's sales and market share and injury to Morton Grove's goodwill and business reputation, warranting injunctive relief.

64. ~~61.~~ The NPA's false and misleading claims were made deliberately and willfully, and the NPA knew or should have known that these statements were false and that the impact of its statements would be to reduce sales of Lindane medications. Therefore, Morton Grove seeks a finding that this is an exceptional case, requiring an award of attorney fees to Morton Grove.

65. ~~62.~~ The NPA's continued use of false or misleading advertising claims is causing great irreparable injury to Morton Grove, thereby warranting an order granting permanent injunctive relief.

**COUNT II**  
**TRADE DISPARAGEMENT**

66. ~~63.~~ Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through ~~62~~65 of this Complaint.

67. ~~64.~~—The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs ~~23~~26 through ~~42~~45.

68. ~~65.~~—The statements regarding Lindane medications set forth in Paragraphs ~~23~~26 through ~~42~~45 are false and misleading.

69. ~~66.~~—The NPA published and communicated these statements through its website and other means.

70. ~~67.~~—When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove.

71. ~~68.~~—As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs ~~45~~48 through ~~49~~52.

**COUNT III**  
**ILLINOIS DECEPTIVE TRADE PRACTICES ACT (815 ILCS 510/2)**

72. ~~69.~~—Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through ~~68~~71 of this Complaint.

73. ~~70.~~—The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs ~~23~~26 through ~~42~~45.

74. ~~71.~~—The statements regarding Lindane medications set forth in Paragraphs ~~23~~26 through ~~42~~45 are false and misleading.

75. ~~72.~~ When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove. Specifically, prior to filing its Complaint, Morton Grove provided the NPA with specific scientific proof that certain of its statements were false and misleading. The NPA did not substantively respond to Morton Grove's letter.

76. ~~73.~~ These statements violated multiple sections of 815 ILCS 510/2, including subsections (2), (7), (8), and (12).

77. ~~74.~~ As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs ~~45~~48 through ~~49~~52.

**WHEREFORE,** Plaintiff, MORTON GROVE PHARMACEUTICALS, INC., requests this Honorable Court for the following relief:

A. An Order (i) permanently enjoining the NPA from further dissemination of false, misleading, and deceptive statements regarding Morton Grove and Lindane medications; (ii) permanently enjoining the NPA from future publication of the false, misleading, and deceptive statements contained in Paragraphs ~~23~~26 through ~~42~~45; and (iii) requiring the NPA to publish corrective advertising;

B. Morton Grove's court costs and reasonable attorney's fees; and

C. For such other and further relief as this Court deems equitable and just.

Dated: ~~March 7,~~July 24, 2008

Respectfully Submitted,

MORTON GROVE  
PHARMACEUTICALS, INC.

By: s/ W. Gordon Dobie  
*One of its Attorneys*

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